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Brown et al.

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(54) **SYSTEM AND METHOD FOR MANAGING HEALTH DATA**

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G16H 10/60 (2018.01)
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CPC G16H 10/60; G16H 40/40; G16H 40/63; G06F 19/00; G06F 17/30312; G06F 8/71;
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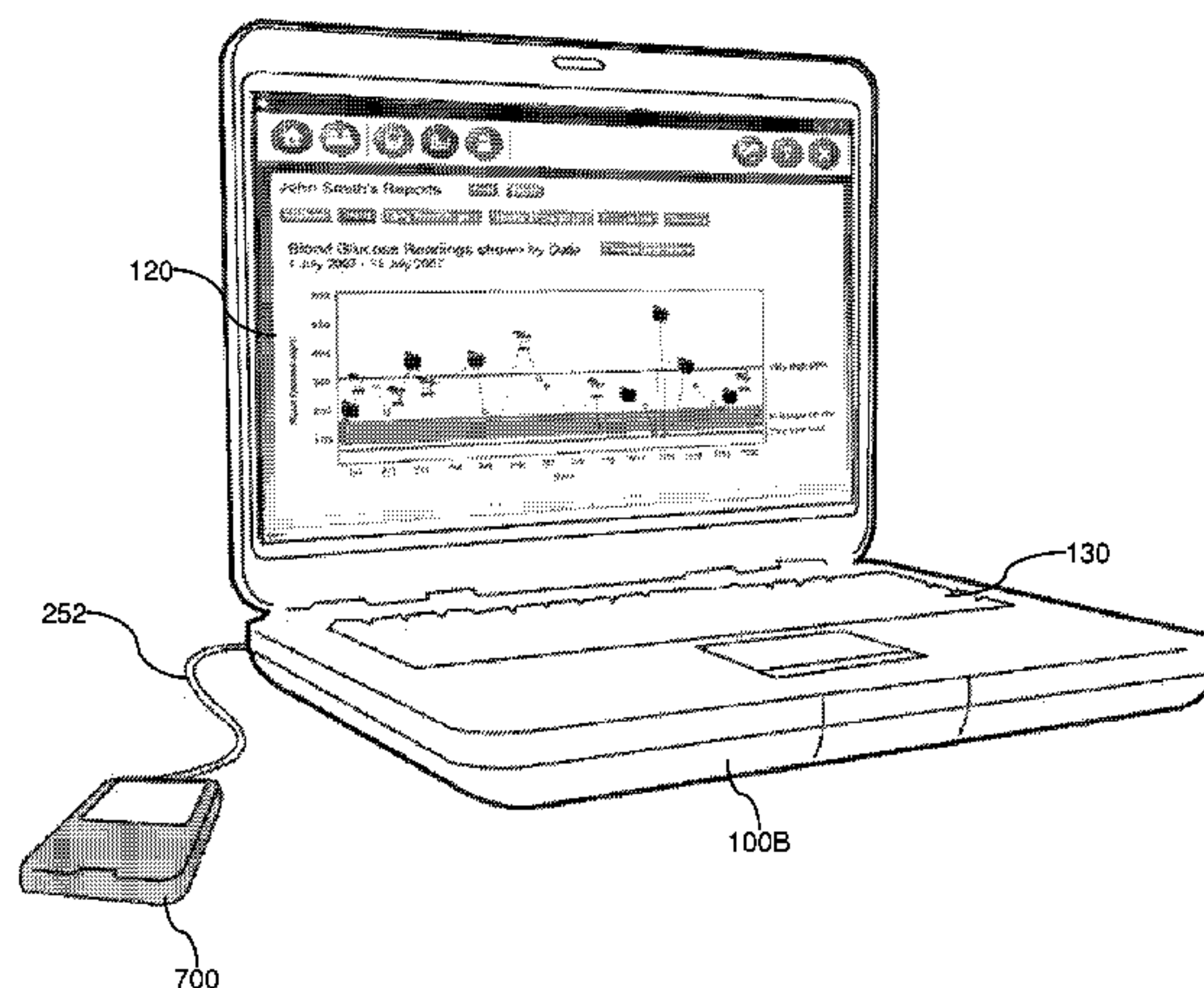
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(57) **ABSTRACT**

A portable data-management system may be easily employed with multiple processing devices by eliminating the need to pre-install additional programs, agents, device drivers, or other software components on the hosts. A portable storage device contains software for a data-management application, which receives and processes test data
(Continued)



from a meter that measures an analyte. The portable device may employ an interface protocol that makes the portable device immediately compatible with different operating systems and hardware configurations. Once the portable device is connected to the host, the data-management application can be automatically launched. The convenience and portability of a data-management system may be enhanced by integrating advanced data processing and display features with the portable device. The users may access some advanced presentations of health data without having to launch the data-management application on a separate host.

17 Claims, 16 Drawing Sheets

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 See application file for complete search history.

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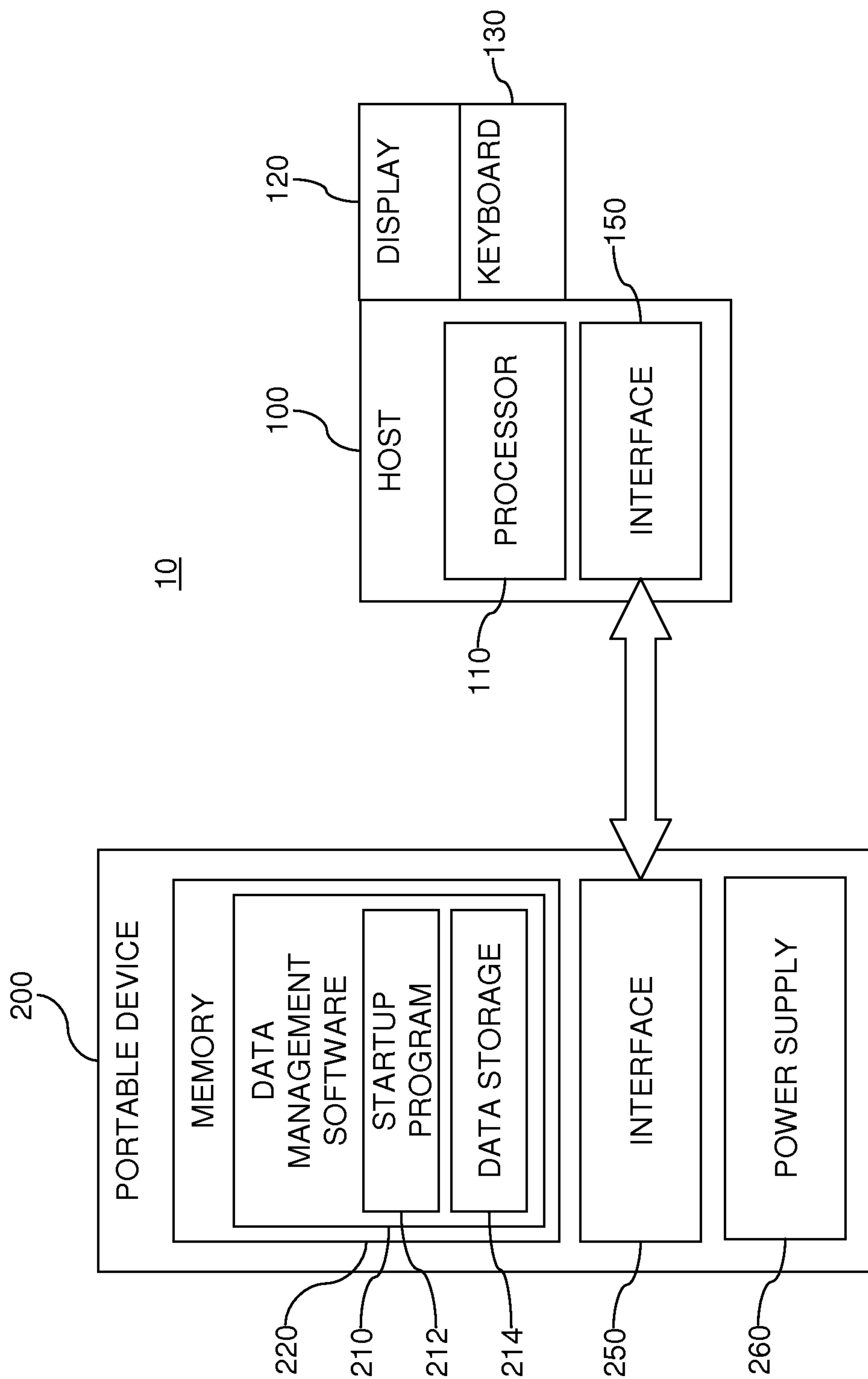


FIG. 1A

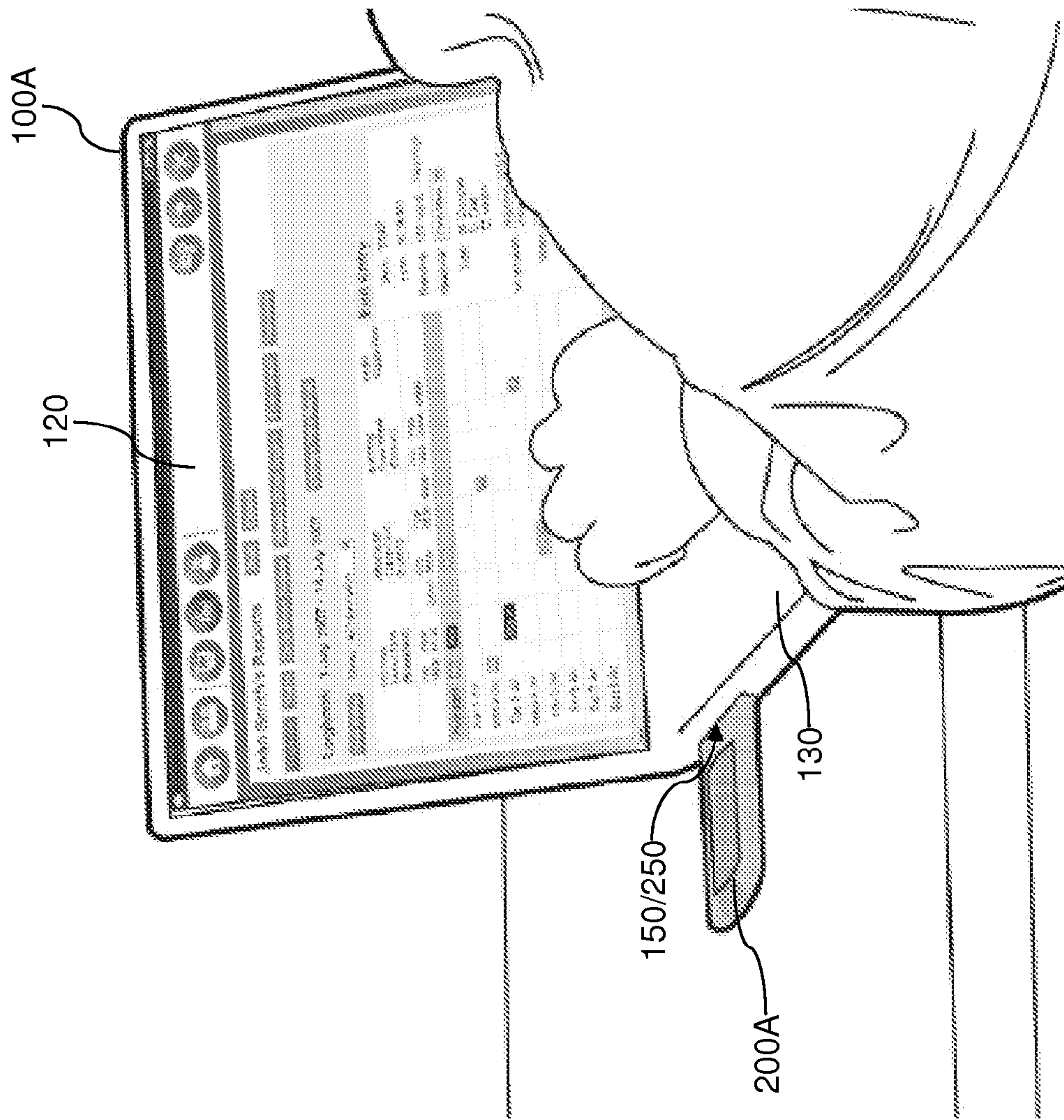


FIG. 1B

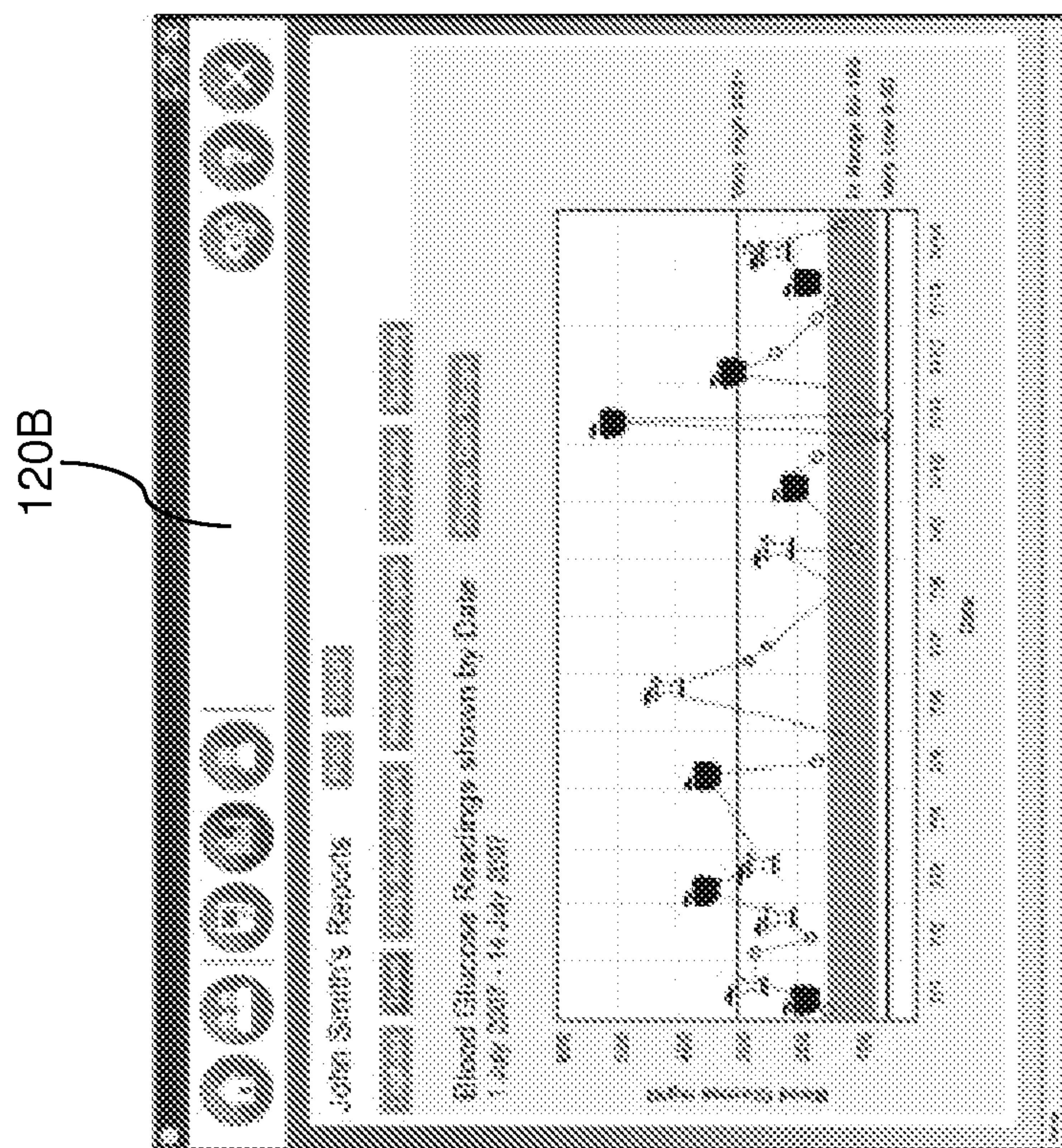


FIG. 1D

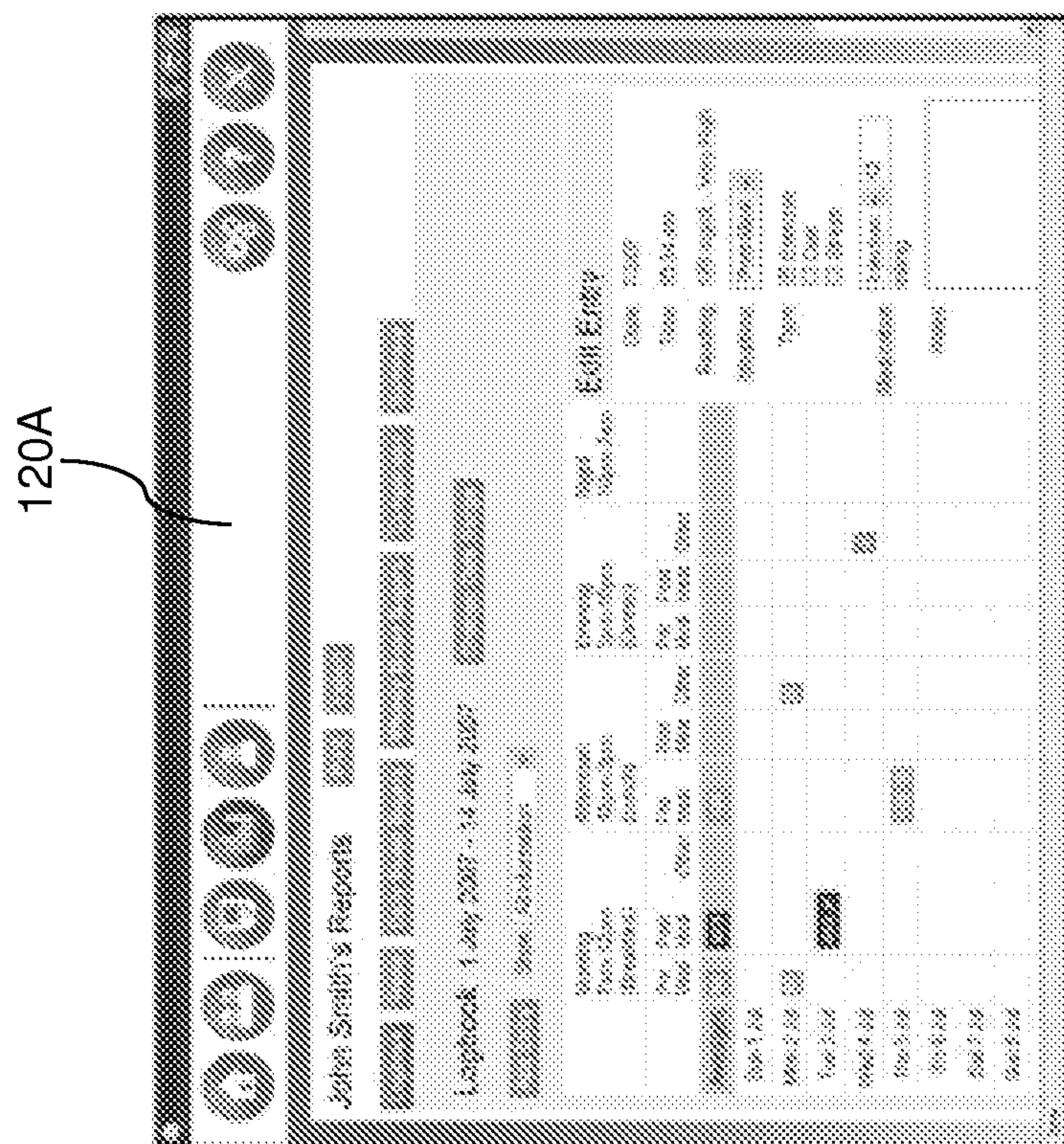


FIG. 1C

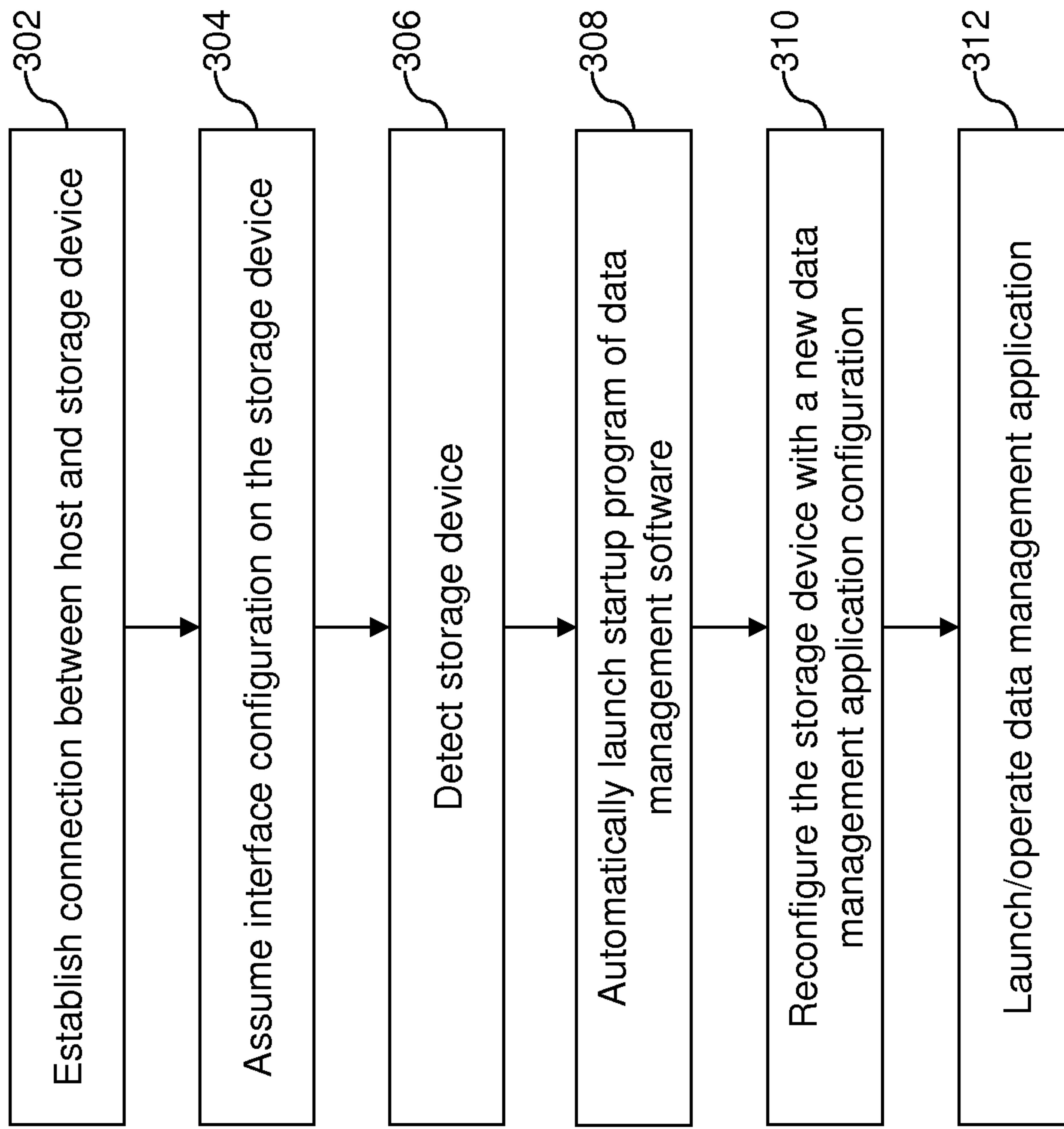


FIG. 2

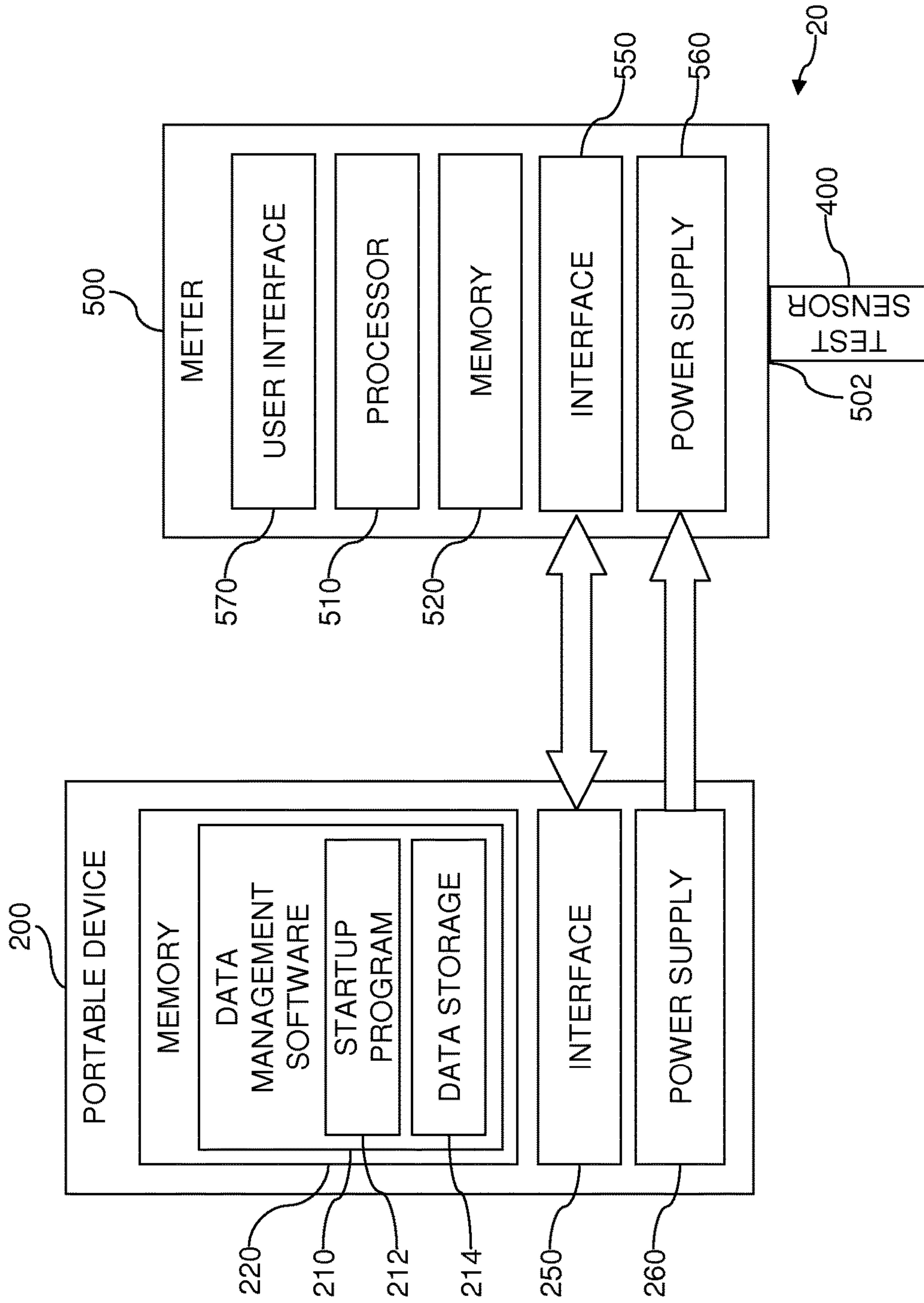


FIG. 3

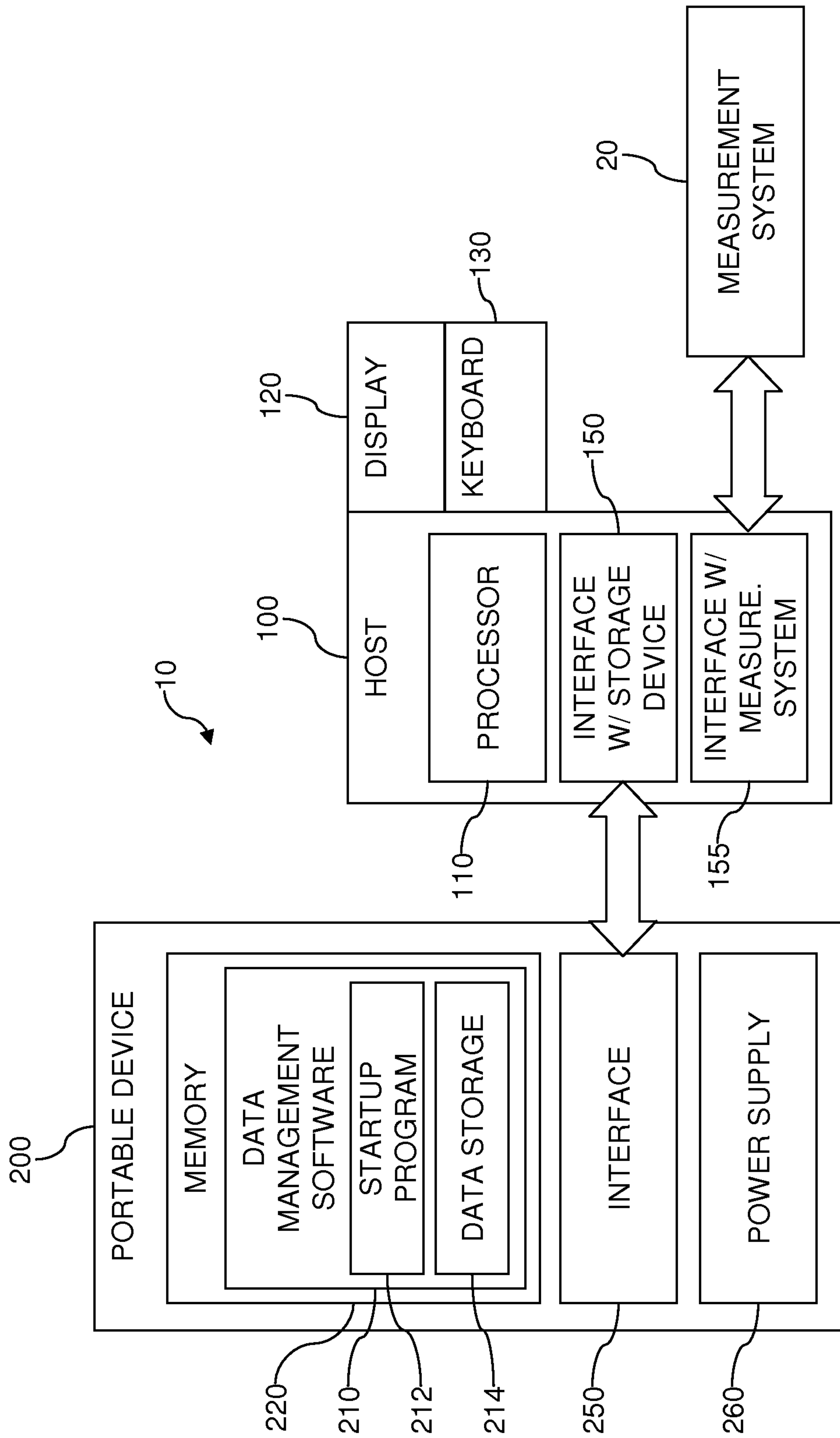


FIG. 4

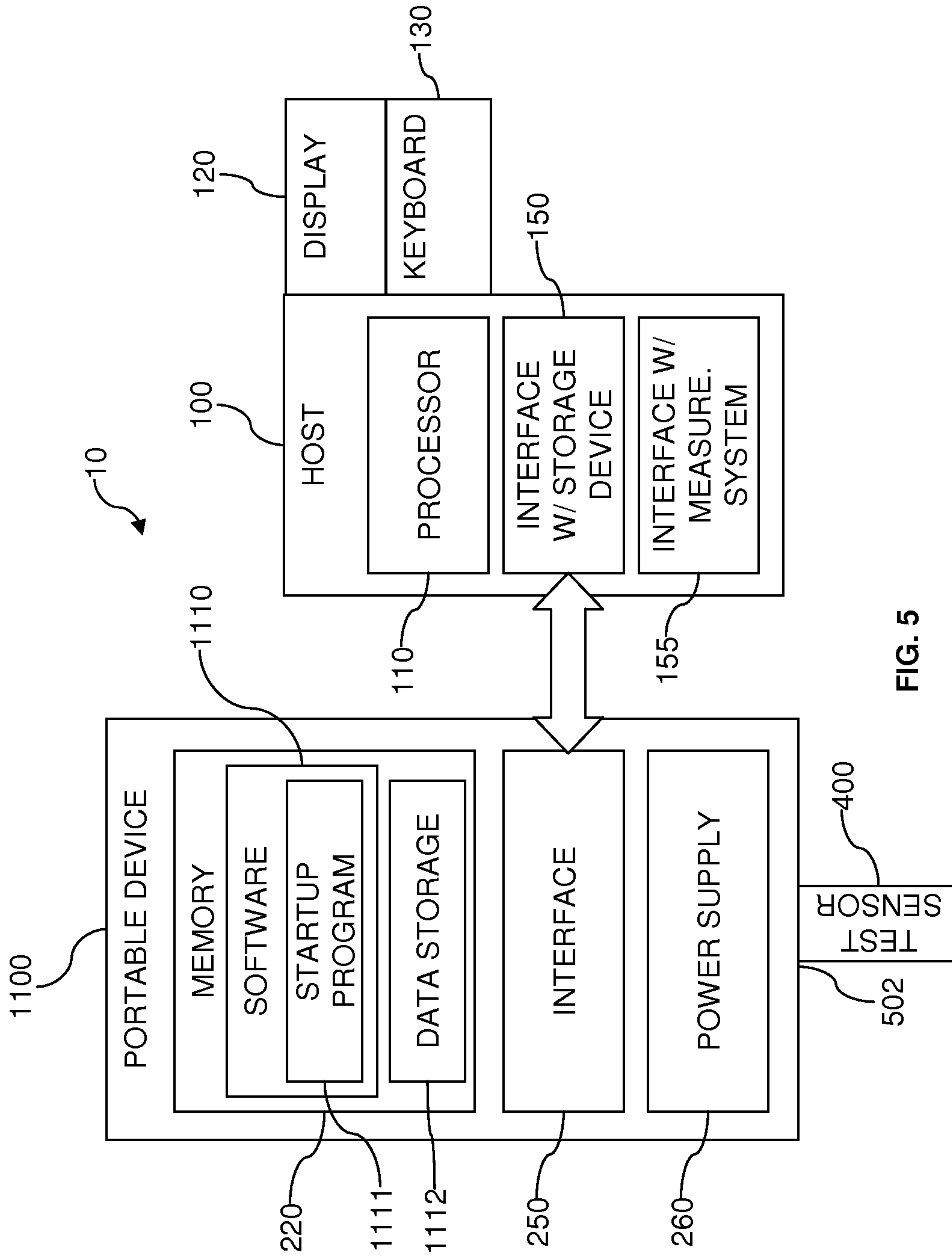


FIG. 5

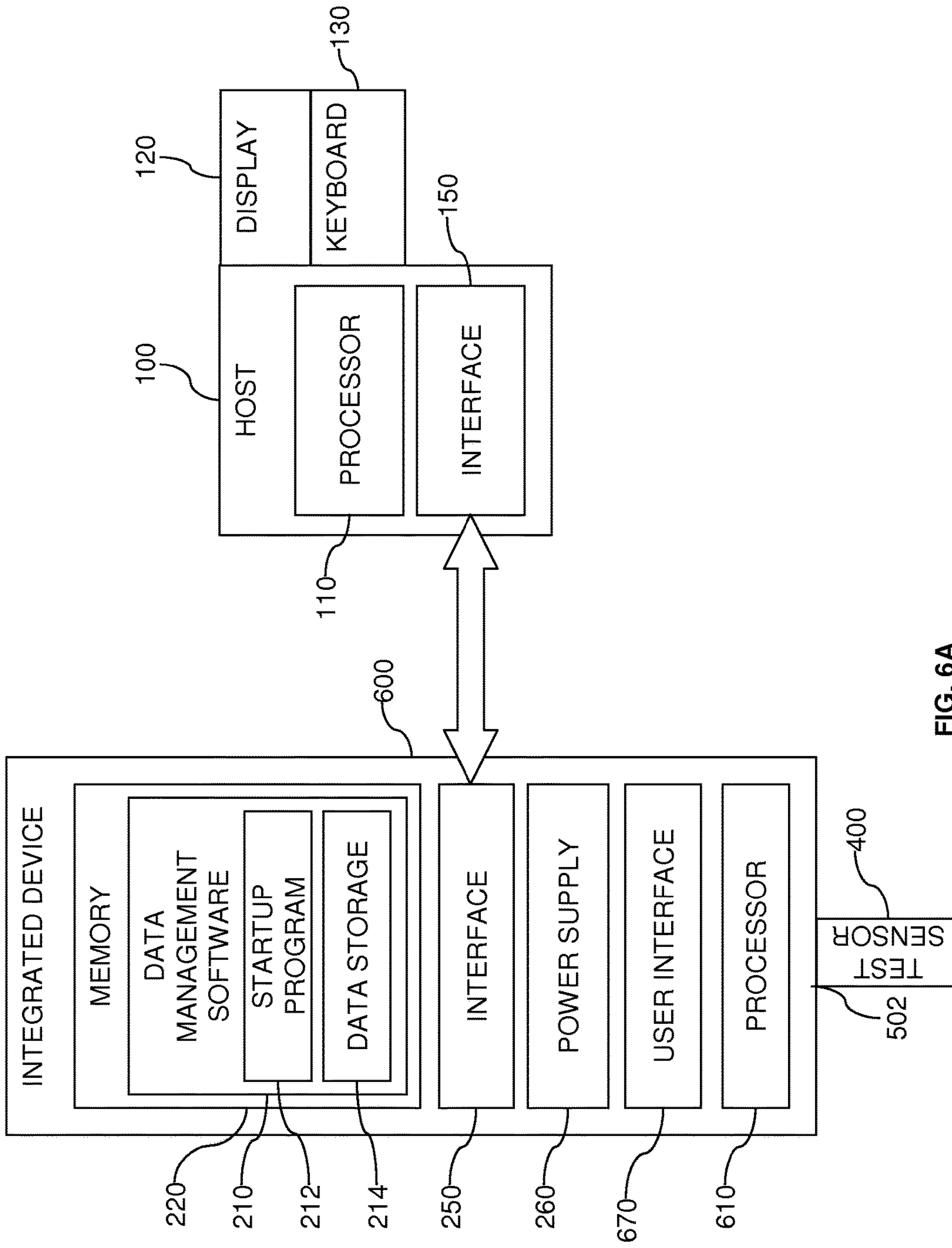


FIG. 6A

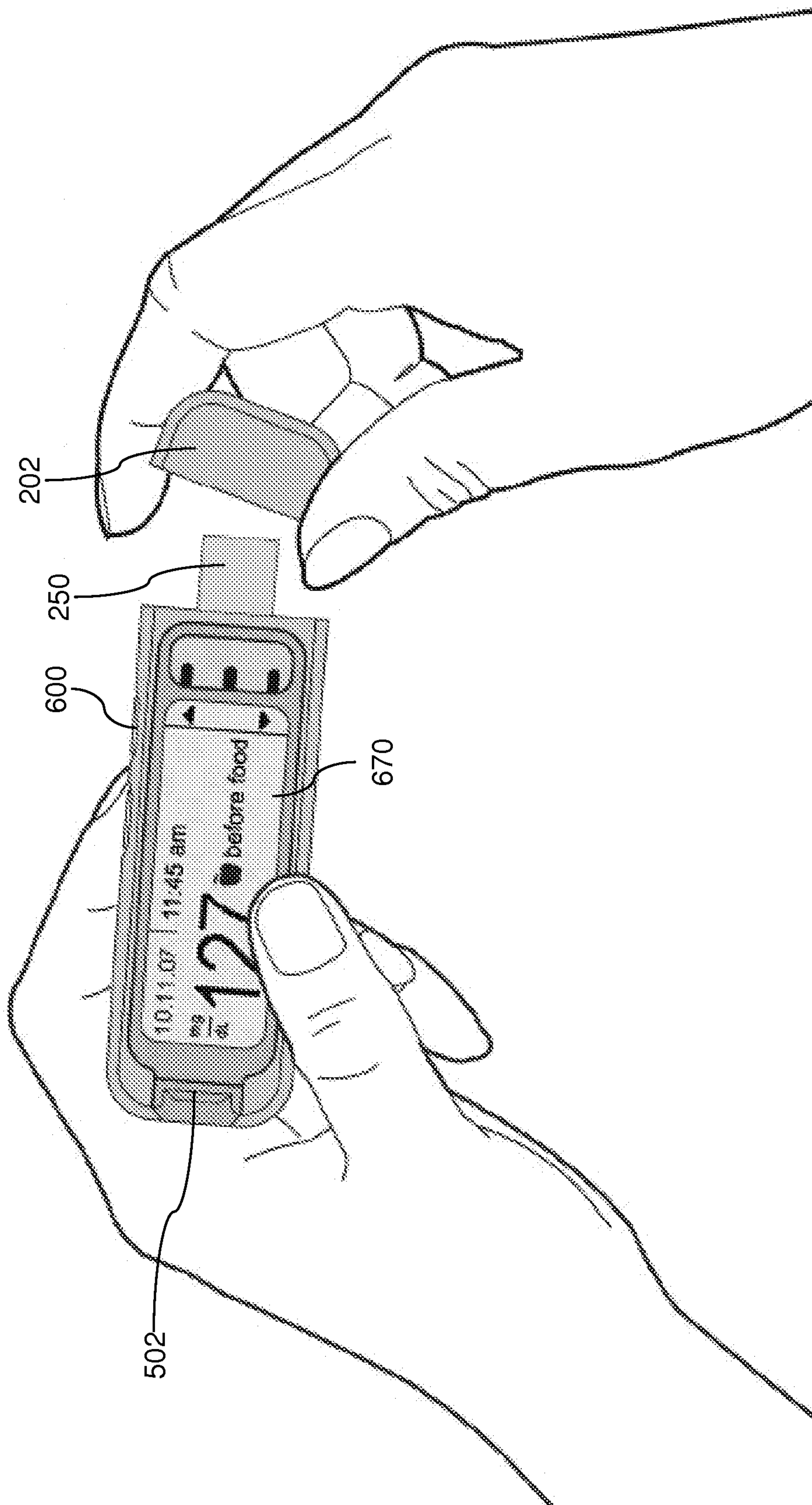


FIG. 6B

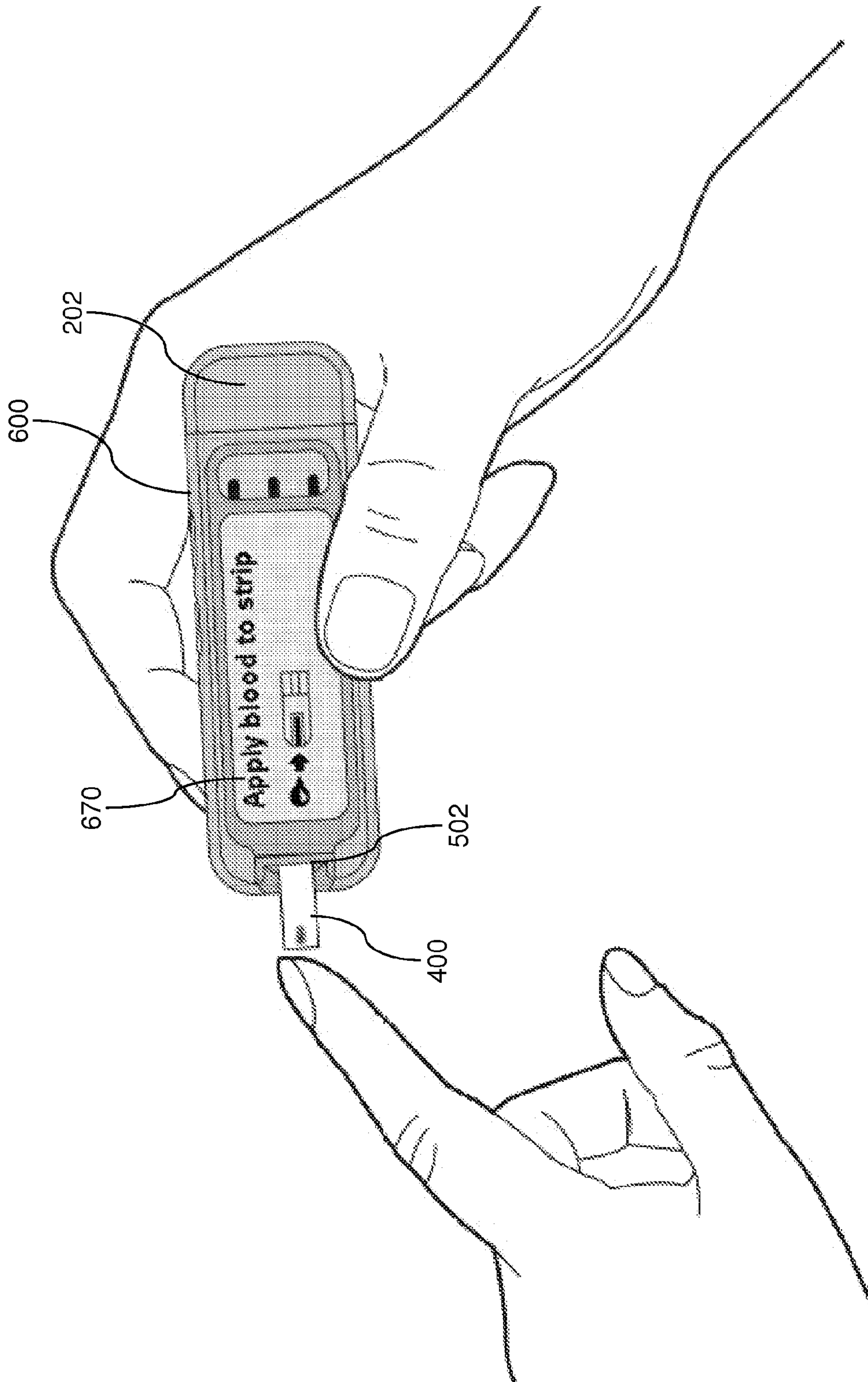


FIG. 6C

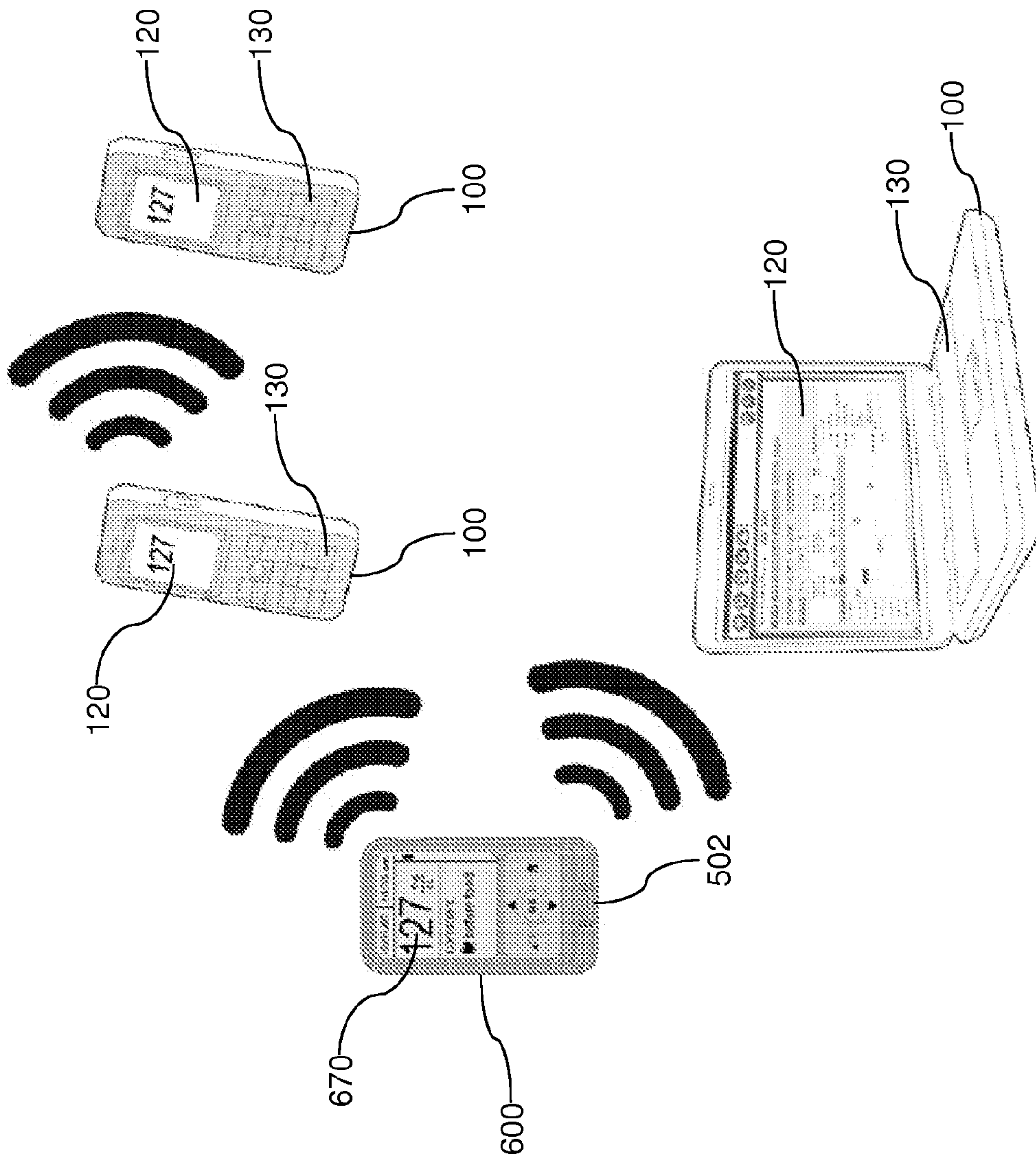


FIG. 6D

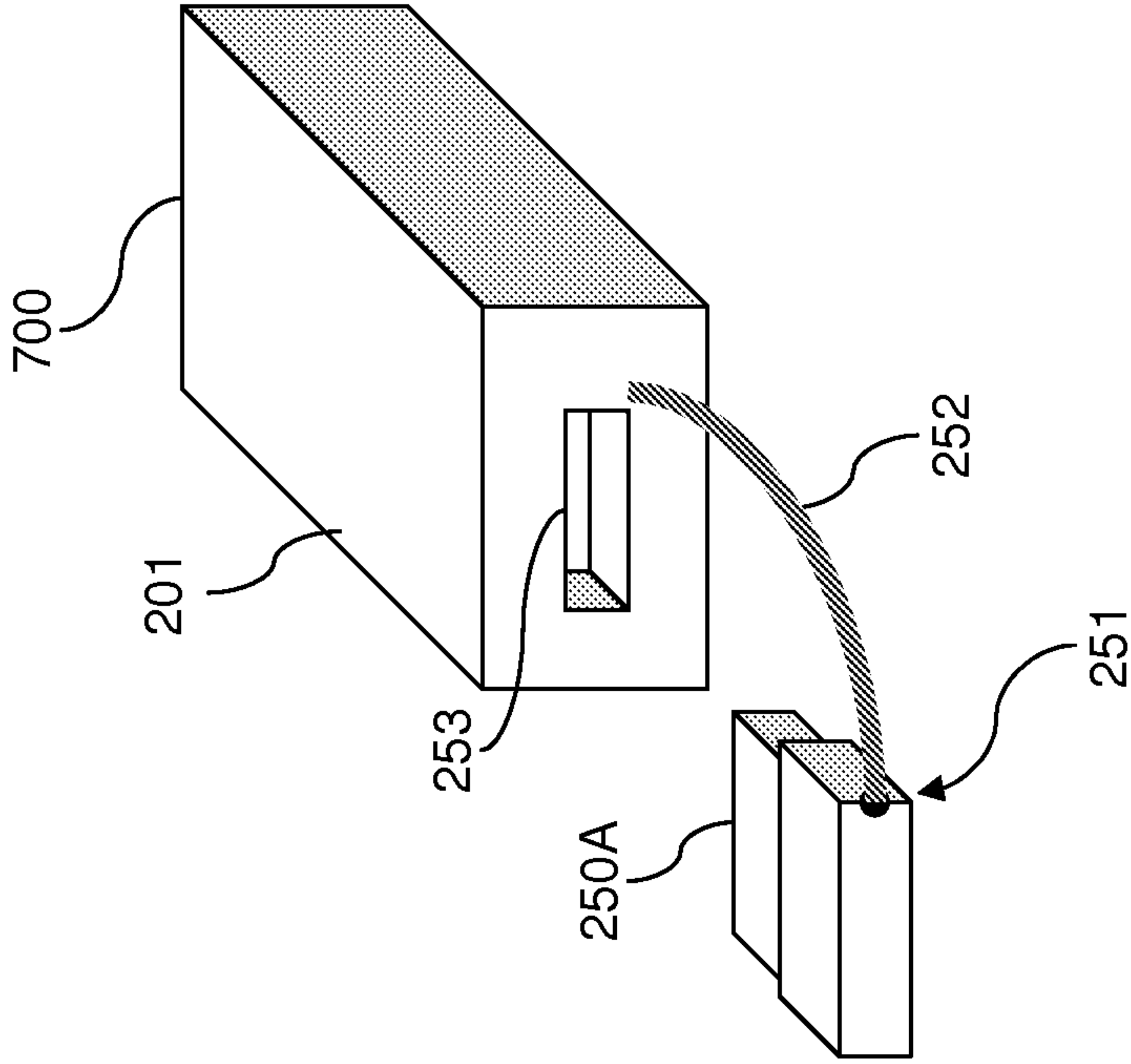
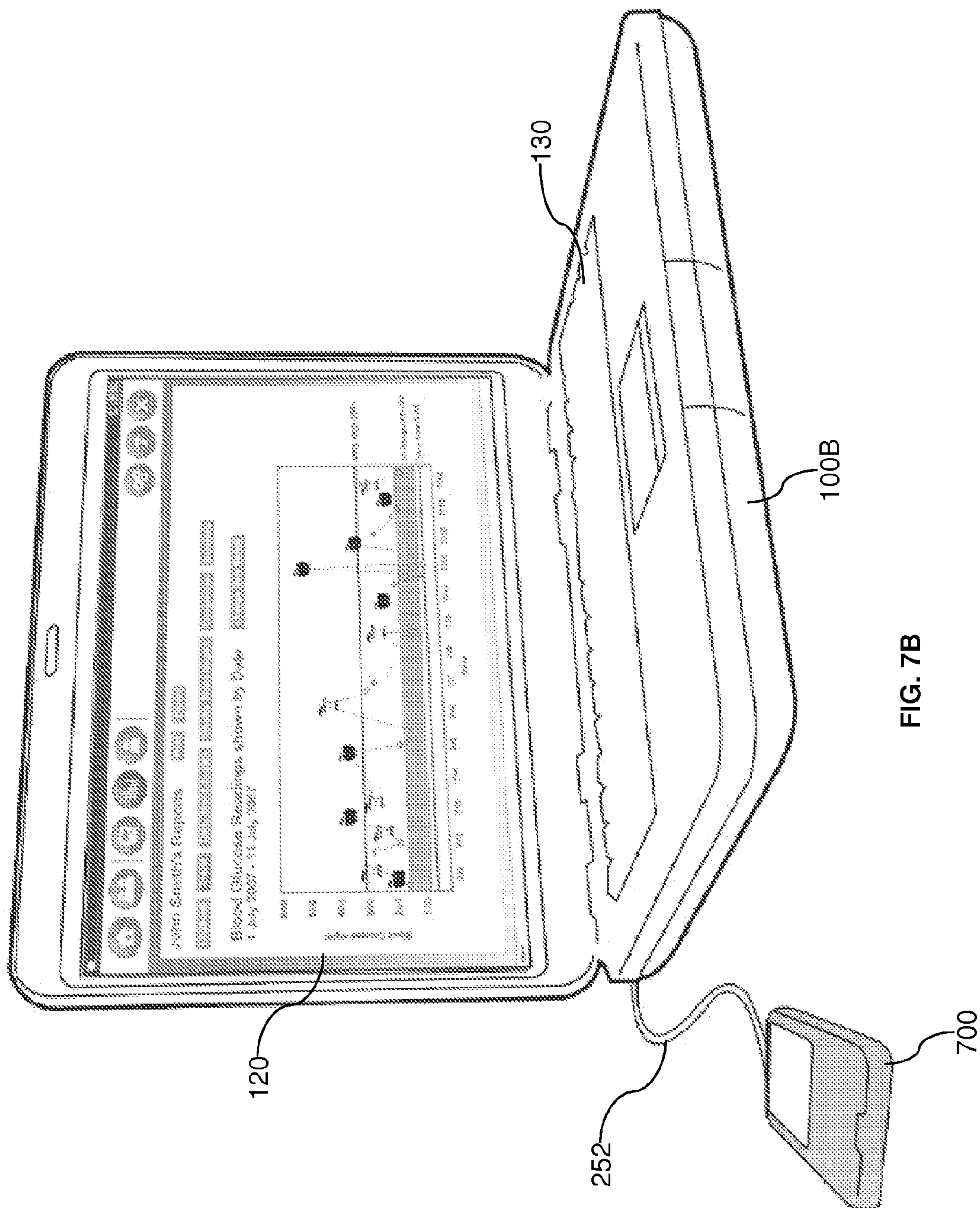


FIG. 7A



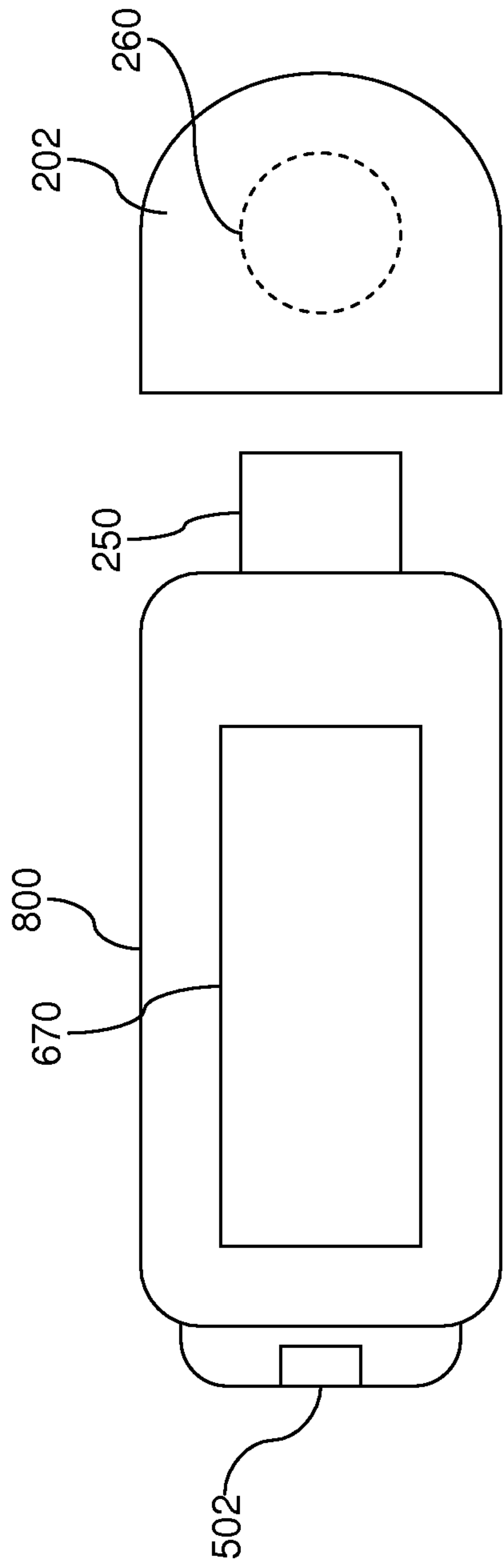


FIG. 8A

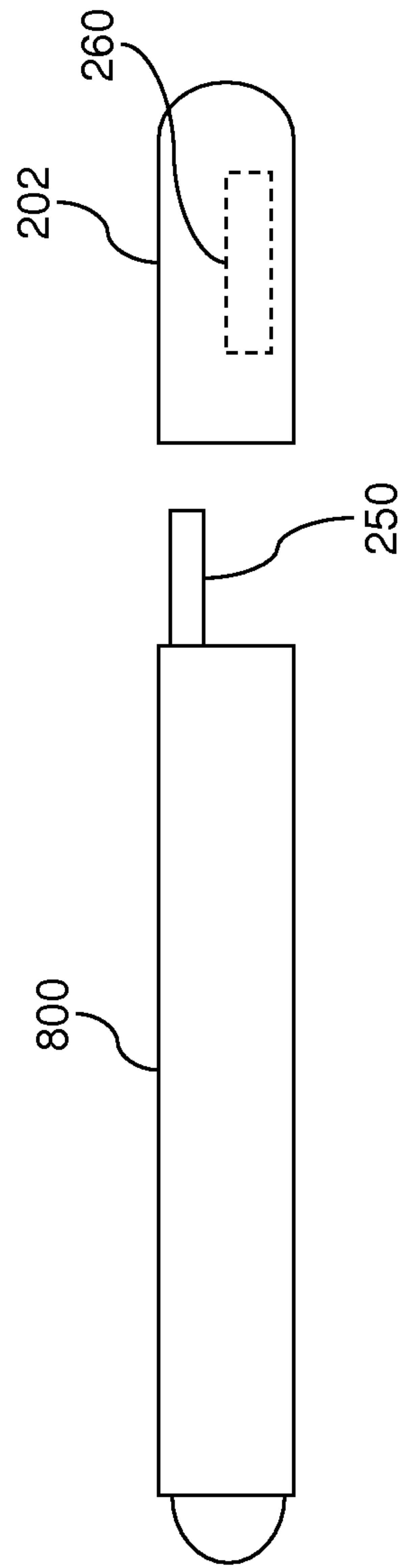


FIG. 8B

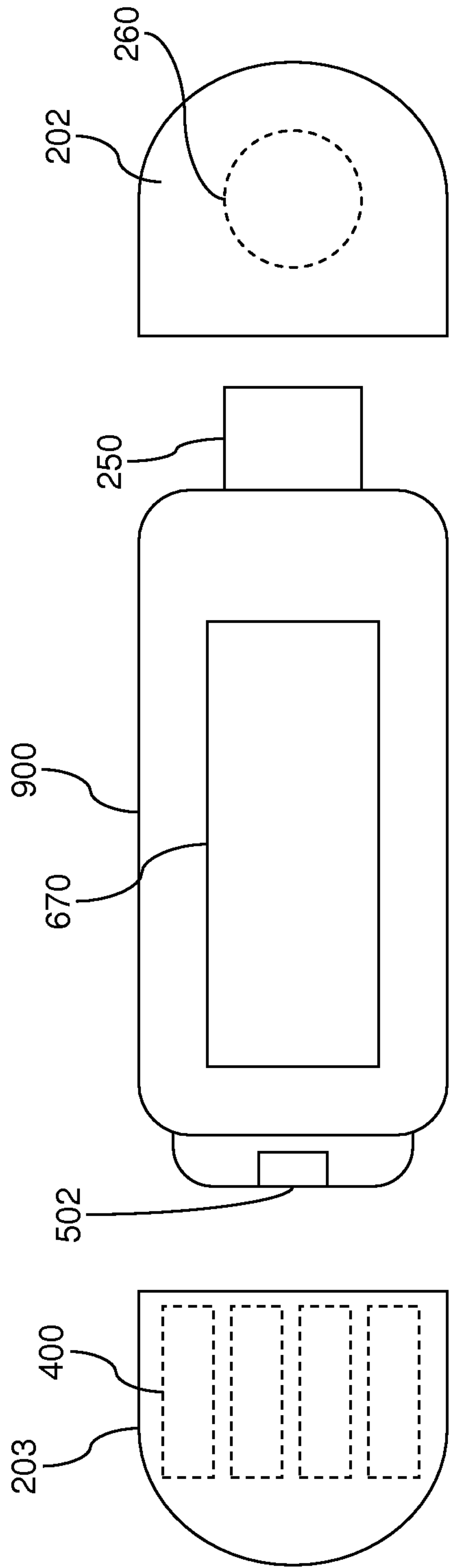


FIG. 9A

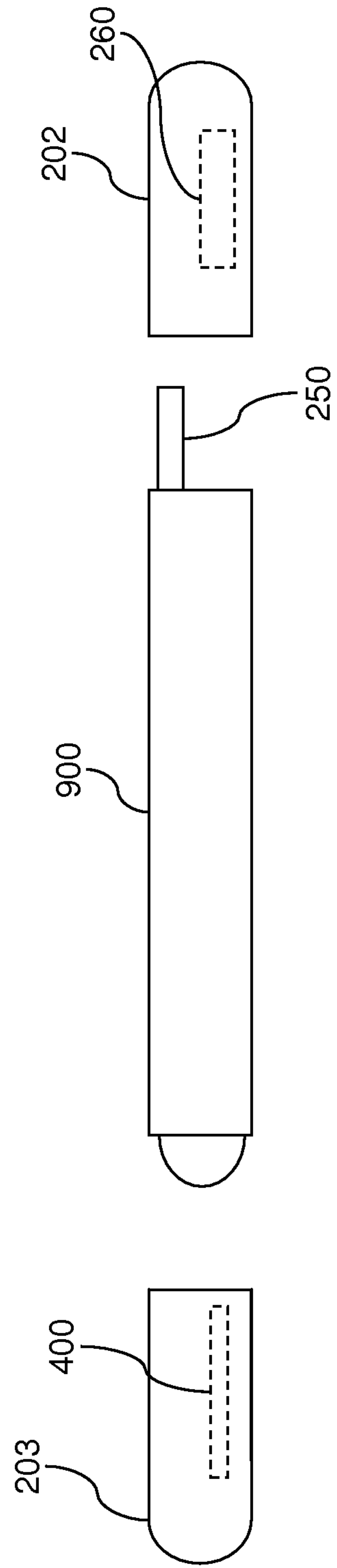


FIG. 9B

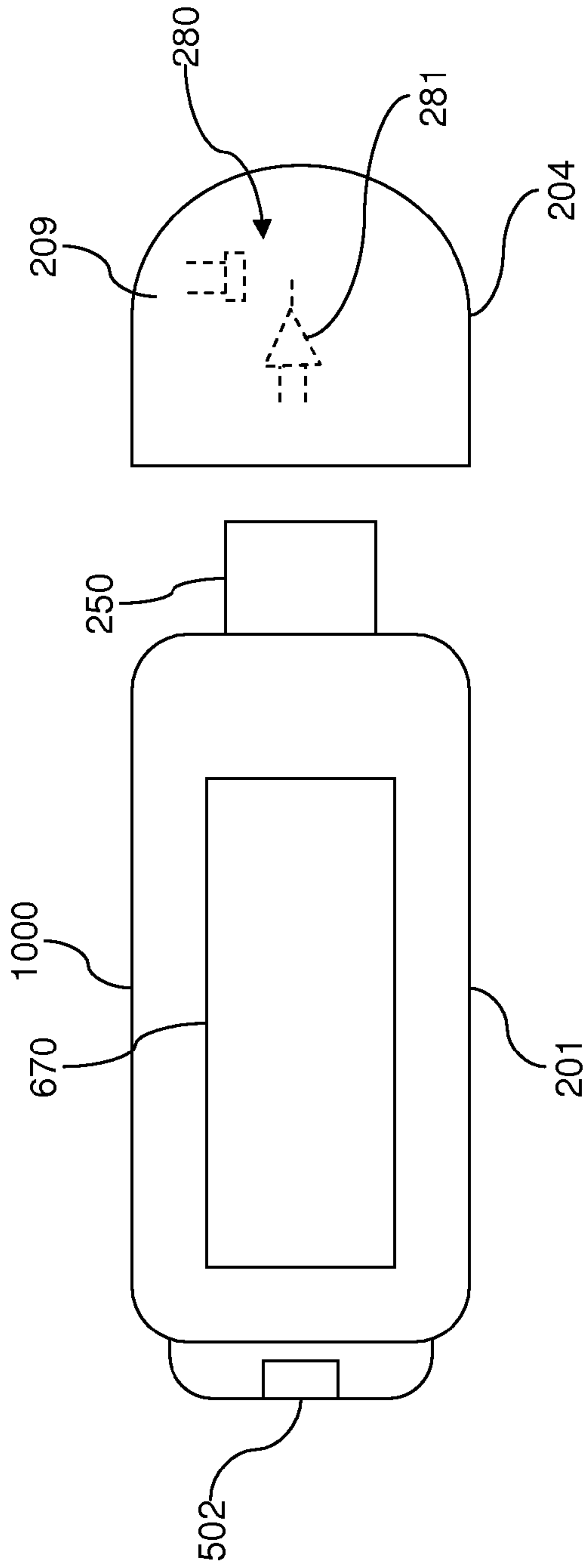


FIG. 10A

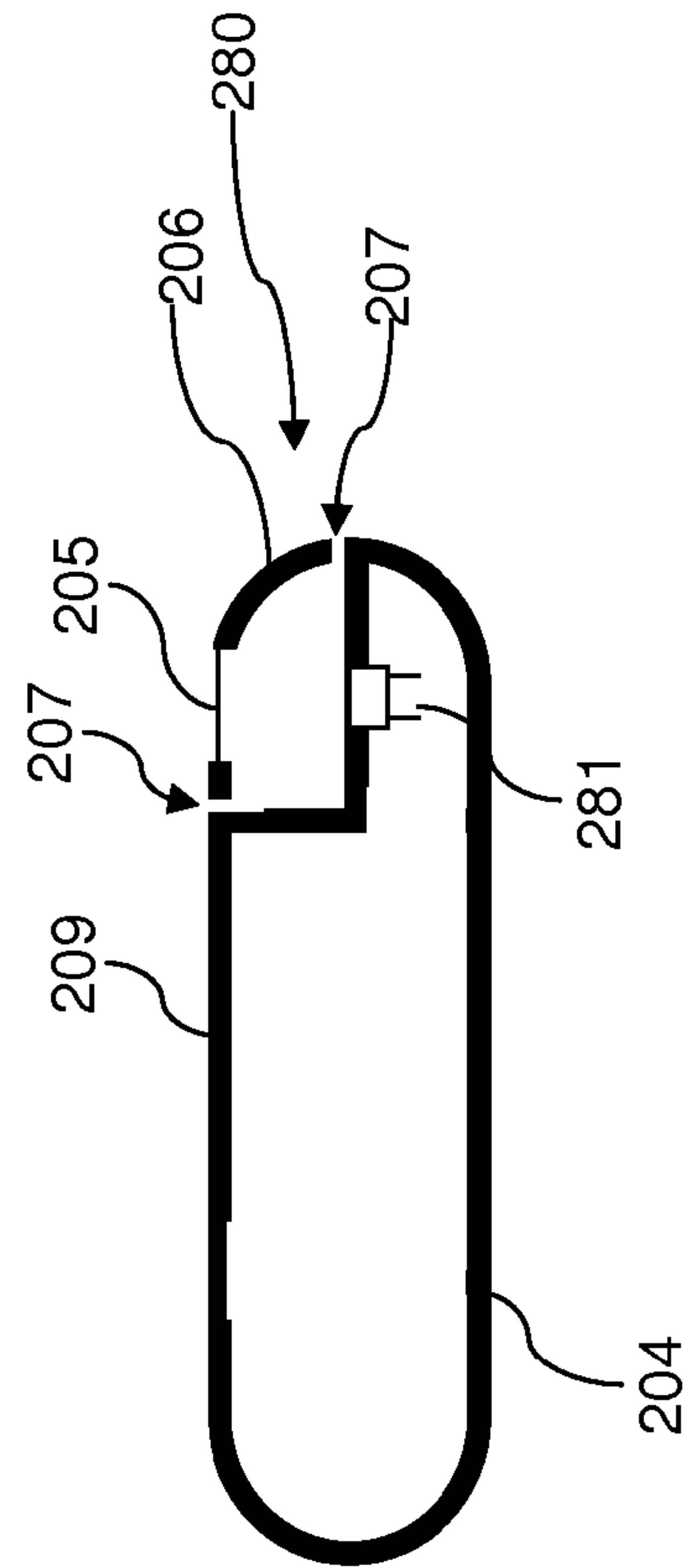


FIG. 10B

SYSTEM AND METHOD FOR MANAGING HEALTH DATA

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/129,547, filed May 29, 2008, now allowed, which claims the benefit of and priority to U.S. Provisional Application No. 60/932,286, filed May 30, 2007, U.S. Provisional Application No. 61/012,721, filed Dec. 10, 2007, and U.S. Provisional No. 61/012,718, filed Dec. 10, 2007, each of which is hereby incorporated by reference herein in its entirety.

FIELD OF THE INVENTION

The present invention relates generally to a method and system for managing health data. More specifically, the present invention relates to a portable system that securely manages and displays information associated with the health of an individual, such as measurements of glucose in a blood sample.

BACKGROUND OF THE INVENTION

The quantitative determination of analytes in body fluids is of great importance in the diagnoses and maintenance of certain physiological conditions. For example, individuals with diabetes frequently check the glucose level in their bodily fluids. The results of such tests can be used to regulate the glucose intake in their diets and/or to determine whether insulin or other medication needs to be administered.

Diagnostic systems, such as blood-glucose systems, may employ an instrument, such as a meter, to calculate the glucose value in a fluid sample from an individual. Such instruments operate by measuring an output, such as current or light, from a reaction with the glucose in the sample. The test results typically are displayed and stored by the meter. Basic systems allow the user to access the test results directly from the meter via a keypad or other interactive component.

SUMMARY OF THE INVENTION

A portable data-management system is provided for securely managing and displaying information associated with the health of an individual, such as measurements of glucose in a blood sample.

One embodiment provides a system for managing health data, comprising: a data storage system storing health data, data-management software, and an initialization program, the initialization program launching the data-management software on a processing device and the data-management software processing the health data on the processing device; and a data communications interface providing data communications between the data storage system and the processing device, wherein, upon establishment of the data communications between the data storage system and the processing device, the initialization program launches the data-management software on the processing device without requiring prior installation, on the processing device, of an additional program component associated with the data-management software.

Yet another embodiment provides a system for managing health data, comprising: a portable device including data-management software that processes health data, the por-

table device having a first software configuration corresponding to an interface protocol and a second software configuration specific to the data-management software; and a processing device connected to the portable device, wherein upon connection between the portable device and the processing device, the processing device communicates with the portable device according to the interface protocol, and after the portable device is reconfigured from the first configuration to the second configuration, the processing device executes the data management software.

A further embodiment provides a method for managing health data, comprising: establishing, for a first time, data communications between a data storage system to a processing device via a data communications interface, the data storage system storing health data, data-management software, and an initialization program; executing, on the processing device, the initialization program upon establishment of the data communications between the data storage system and the processing device, without requiring prior installation, on the processing device, of an additional program component associated with the data-management software; launching, with the initialization program, the data-management software on the processing device; and processing the health data on the processing device with the data-management software.

Another embodiment provides a method for managing health data, comprising: detecting a connection between a portable device and a processing device, the portable device containing data-management software processing health data and having a first software configuration corresponding to an interface protocol, wherein upon connection between the portable device and the processing device, the processing device communicates with the portable device according to the interface protocol; reconfiguring the portable device from the first configuration to a second configuration specific to the software; and launching the software from the reconfigured portable device.

Yet a further embodiment provides a system for managing health data, comprising: a first device that stores health data, data-management software, and an initialization program; a second device that processes the health data with the data-management software; and a data communications interface providing data communications between the first device and the second device, wherein upon establishment of the data communications between the data storage system and the processing device, the initialization program launches the data-management software on the processing device without requiring prior installation, on the processing device, of an additional program component associated with the data-management software.

An additional embodiment provides a device for managing health data, comprising: a first housing portion including a data storage system that stores health data; and a second housing portion including a data communications element that provides data communications between the data storage system and a processing device by connecting with the processing device, the processing device processing the health data according to a data-management software, wherein the first housing portion and the second housing portion are connected by a cable that communicates signals between the data communications element and other components in the first housing portion.

A further additional embodiment provides a device for managing health data, comprising: a first housing portion including a health data management system and a data communications element that provides data communications between the health data management system and an external

processing device; and a second housing portion that is removably coupled to the first housing portion, the second housing portion including at least one component used by the health data management system.

Still other aspects, features, and advantages of the present invention are readily apparent from the following detailed description, by illustrating a number of exemplary embodiments and implementations, including the best mode contemplated for carrying out the present invention. The present invention is also capable of other and different embodiments, and its several details can be modified in various respects, all without departing from the spirit and scope of the present invention. Accordingly, the drawings and descriptions are to be regarded as illustrative in nature, and not as restrictive. The invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A illustrates a data-management system including a portable device connected to a processing device.

FIG. 1B illustrates an example of the data-management system of FIG. 1A.

FIG. 1C illustrates an example of a display for the data-management system of FIG. 1A.

FIG. 1D illustrates another example of a display for the data-management system of FIG. 1A.

FIG. 2 illustrates a flowchart for launching a data-management application from a portable device.

FIG. 3 illustrates a data-management system including a portable device connected to a measurement system.

FIG. 4 illustrates a data-management system including a portable device and a measurement system both connected to the same processing device.

FIG. 5 illustrates a data-management system including a portable device that receives a test sensor and operates with a processor and a user interface of a processing device.

FIG. 6A illustrates a data-management system including an integrated device that provides a measurement system and a user interface.

FIG. 6B illustrates the integrated device of FIG. 6A with a USB interface element.

FIG. 6C illustrates the integrated device of FIG. 6A receiving a test sensor for receiving a sample.

FIG. 6D illustrates the integrated device of FIG. 6A connected wirelessly to a plurality of processing devices.

FIG. 7A illustrates a portable device with a USB interface element on an extendible cable.

FIG. 7B illustrates a system with the portable device of FIG. 7A connected to a processing device.

FIG. 8A illustrates a view of a portable device with a battery pack stored in an end cap.

FIG. 8B illustrates another view of the portable device of FIG. 8A.

FIG. 9A illustrates a view of a portable device with a battery stored in a first end cap and sensor strips stored in a second end cap.

FIG. 9B illustrates another view of the portable device of FIG. 9A.

FIG. 10A illustrates a view of a portable device with a temperature sensor stored in an end cap.

FIG. 10B illustrates a view of a temperature sensor that may be employed in the end cap of FIG. 10A.

DESCRIPTION OF ILLUSTRATED EMBODIMENTS

A portable data-management system is provided for securely managing and displaying information associated

with the health of an individual, such as measurements of glucose in a blood sample. The data-management system is advantageous to individuals who are actively involved in monitoring and recording measurements of their blood glucose concentrations and/or other analytes or fluids of interest. Individuals who test frequently can more easily manage their test results as well as other health data with the data-management system. The data-management system may be employed with different processing devices at varying locations, as there is essentially no need to pre-install additional programs, agents, device drivers, or other software components on the separate processing devices to operate the data-management system. A portable device stores software for a data-management application that receives and processes test results and other health data. The portable device may employ an interface protocol that is compatible with the operating systems and hardware configurations of different types of processing devices. Once the portable device is connected to a processing device, the data-management application may be launched on the processing device.

The data-management system also may integrate advanced data processing and display features with the portable device. As such, the users may access some advanced presentations of health data without launching the data-management application on a separate processing device. In addition, the data-management system may integrate other functions, such as an analyte measurement function, with the portable device.

Due to the portability of the data-management system, the data-management system also addresses issues related to the security of data, such as personal medical information. The data-management system ensures that all data is stored on the portable device in the user's possession and that no data is transferred to and stored by other processing devices. Thus, a user may use a public computer to interface with the portable device and no data will remain on the public computer for others to view. Other security functionality, such as user-authentication procedures, may also be implemented to enhance security data. Furthermore, the data-management system may also preserve data integrity during the transfer of data between the portable device and other devices.

FIG. 1A illustrates a data-management system 10 including a processing device 100 and a portable device 200. The processing device 100 may be a desktop or laptop personal computer (PC), a handheld or pocket personal computer (HPC), a compatible personal digital assistant (PDA), a smart cellular phone, or the like. In addition, the processing device 100 may employ any operating system and configuration. If the processing device 100 is a desktop or laptop personal computer, the operating system may be a version of Microsoft® Windows®. Alternatively, if the processing device 100 is a PDA, the operating system may correspond with those of PALM® handhelds from Palm, Inc., or BlackBerry® devices from Research in Motion Limited. In general, the processing device 100 includes a processor 110 that is capable of receiving and executing any number of programmed instructions. In addition, the processing device 100 is typically operated with a display 120 and a keyboard 130, and/or other input/output elements, which may be external to, or integrated with, other components of the processing device 100.

As described in greater detail below, the portable device 200 may be employed in combination with hosts that can execute tasks but that are not full-function processing devices. Such hosts may include task specific devices such

as printers, display devices, fluid analyte meters (e.g., blood glucose meters), or the like. In general, while a particular configuration of the data-management system may be described, other configurations may be used including those employing other hosts, storage devices, and additional components.

The portable device **200** may be sized to be easily carried, transported, and stored by an individual. The portable device **200** may include a memory, or data storage, **220**, such as flash memory, Electrically Erasable Programmable Read-Only Memory (EEPROM), or the like. The memory **220** may be configured to include a combination of storage technologies. The memory **220** stores data-management software **210** associated with the data-management system **10**. The data-management software **210** may be a collection of programs or computer code that receives and processes measured data and/or other input. The data-management software **210** processes and/or displays this input in a manner that is desired or selected by the user or other individuals. This information may be used by a user, home care provider (HCP), a physician, and/or other individuals. As discussed previously, the measured data may include information from the testing of an analyte including the concentration of glucose and/or other analytes in a person's blood or other fluid. The software **210** can provide the advanced displays and data processing that may be required by a user who tests multiple times a day (e.g., from about six to about ten times a day). For example, the software **210** may include a product similar to WINGLUCOFACTS® Diabetes Management Software available from Bayer HealthCare LLC (Tarrytown, N.Y.). As such, the software **210** may provide a complete tool kit that receives and stores test results from a blood glucose-measurement system, receives and stores other testing information, such as test times and meal markers, tracks test results in an electronic logbook, calculates averages and provides other statistical analysis, summarizes and provides feedback on the test results, provides a customizable graphical user interface, displays user-friendly charts and graphs of the test results, tracks test results against user-specific target ranges, provides predictive analysis, and/or sends data to healthcare professionals via fax, email, or the like. FIG. 1C illustrates an exemplary display **120A** presenting test results from a blood glucose-measurement system in an electronic logbook format, while FIG. 1D illustrates an exemplary display **120B** presenting similar data as a graphical trend analysis. The memory **220** may also include other software in addition to the software **210**.

The data-management system **10** is not limited to receiving and managing information from the testing of an analyte, such as blood glucose. Indeed, the data-management system **10** may receive data from other systems or devices that measure and/or record health data and do not require analyte testing, such as body-temperature measurements, blood-pressure measurements, heart rate measurements, blood-oxygen content measurements, breathing measurements for chronic obstructive pulmonary disease (COPD) analysis, weight measurements for analyzing Lasix use, or the like.

The data-management software **210** may include a combination of software programs or components. In FIG. 1A, the data-management software **210** includes a startup or initialization program **212** that initiates the data-management application. The startup program **212** can identify the relevant capabilities and platform of the processing device **100** so that a platform-compatible application may be selected and launched for execution on the processing device **100**. As such, the software **210** may be compatible

with one or more platforms/operating systems. Greater compatibility of the software **210** enhances the portability of the data-management system **10**.

In addition, the software **210** may employ data storage **214**, such as an embedded database, for receiving and storing test results. The data-management system **10** addresses issues related to the security of data, such as personal medical information, by ensuring: (1) essentially all data is stored and processed on the portable device **200**, which remains in the user's possession; and (2) no readable data is permanently transferred from the data storage **214** to the processing device **100**, which other individuals may access. Thus, a user may use a public computer to interface with the data-management system **10** and no data remains on the public computer for others to view. Although the data-management system **10** may temporarily transfer data to RAM or other similar storage on the processing device **100**, a cleanup or termination procedure in the software **210** ensures that any such transferred data is removed from the processing device **100** when execution of the software **210** is terminated. However, as described further below, the software **210** may be executed directly from the portable device **200**, so that no memory, e.g. RAM, on the processing device **100** is used to hold any data even temporarily.

If a particular processing device **100** is trusted by a user and/or is frequently employed by the user, the user may register the processing device **100** with the portable device **200** to allow data transfer to the processing device **100**. A unique device identifier for the processing device **100** may be recorded on the portable device **200**, so that the portable device **200** can recognize the processing device **100** and permit data transfer to the processing device **100**.

Data security may also be enhanced by employing the data storage **214** (e.g., an embedded database) that can only be accessed or decrypted by the data-management software **210**. Furthermore, the software **210** may also include programs or components, such as user-authentication routines, that protect data integrity and security. When the data-management software **210** launches, it may immediately prompt the user for a user ID and password, personal identification number (PIN), and/or other authentication information. The user is only allowed access to data on the portable device **200** if the response to the security prompt corresponds with authentication information stored with the data-management system **10**. A user-authentication routine may also be employed to permit data to be transferred from the portable device **200** to the processing device **100**.

In addition, a memory map may be employed where the memory **220** is configured to have multiple security levels. In other words, areas of the memory **220** are designated for different levels of access and manipulation, e.g., some areas may be more restricted than others. For example, a first layer may permit open access for data writes, deletes, and changes, while a second layer may be completely unchangeable. As such, a software kernel, core programs, critical permanent data, and the like may be stored on the second layer to protect the software and the data from corruption or deletion.

As discussed previously, the memory **220** may be configured to include a combination of storage technologies. Accordingly, the software kernel, the data-management software **210**, and the like may be stored on an EEPROM or other primary device. The data-management software **210** is launched on the processing device **100** from the EEPROM. Meanwhile, data processed by the data-management software **210** is stored on a separate flash memory or other memory device on the portable device **200**.

As discussed previously, the portable device **200** may include a flash memory device, such as a universal serial bus (USB) flash drive or a memory card. USB flash drives are also known as thumb drives, handy drives, flash sticks, or jump drives. Memory cards may have a variety of formats, including PC Card (PCMCIA), CompactFlash (CF), Smart-Media (SM/SMC), Memory Stick (MS), Multimedia Card (MMC), Secure Digital Card (SD), xD-Picture Card (xD), Intelligent Stick (iStick), ExpressCard, some variation thereof, or the like. Flash memory devices may employ non-volatile memory so that the software associated with the data-management software **210** may be retained in the portable device **200** even when the portable device **200** receives no power. The portable device **200** may employ other storage media, such as floppy disk or optical disc (CD, DVD, Blu-ray disc).

In some embodiments, the memory **220** in the portable device **200** may include execute-in-place (XIP) memory, such as NOR (NOR digital logic gate) flash memory, so that the data-management software **210** stored on the memory **220** can be executed directly without the need to copy them into RAM on the processing device **100**. Accordingly, the data-management system **10** can secure the data by ensuring that essentially all data is stored and processed by a data-management system **10** running off a portable device in the user's possession and that essentially no data is transferred to other processing devices. Thus, a user may use a public computer to interface with the system and no data will remain on the public computer for others to view.

The portable device **200** may interface with the processing device **100** in a convenient plug-n-play (PnP) approach. The interface enables data communications between the portable device **200** and any processing device **100** and penults the data-management software **210** to be used with the processing device **100**. In particular, the portable device **200** has an interface element **250** that is compatible with an interface element **150** on the processing device **100**. The portable-device interface element **250** may physically engage the processing-device interface element **150** to form a hardware interface. In other words, a physical or wired connection between the processing device **100** and the portable device **200** may be employed. FIG. 1B illustrates a portable device **200A** physically connected, e.g., plugged in, via interface elements **150/250** to a processing device **100A**, which is a laptop PC with a display screen **120** and a keyboard **130**. The portable device **200** may be a USB flash drive, and the processing-device interface element **250** may be a USB connector that is received into a USB port, which acts as the processing-device interface element **150** on the processing device **100**. Thus, the portable device **200** employs a USB mass-portable device (USB MSD) configuration that enables communication between the processing device **100** and the portable device **200** according to a set of standard computing communications protocols. The USB connector on the portable device **200** is easily inserted into and removed from the USB port on the processing device **100**. In addition, adapters may be required to enable connection, for example, between the portable device **200** and a processing device **100** employing mini-USB, micro-USB, or the like. While FIG. 1A shows a single interface element **250**, the portable device **200** may include more than one interface element **250** to enable connections according to more than one interface technology.

USB ports appear on most conventional desktop and laptop PCs, for example, and the USB mass storage standard is supported natively by modern operating systems such as Microsoft® Windows®, Mac OS®, Linux, and other Unix-

like systems. As USB communications are natively supported by a wide variety of devices, additional programs, agents, device drivers, or other software components do not have to be installed locally on the processing device **100** to enable communication with the mass-portable device (USB MSD) configuration of the portable device **200**.

The portable device **200** also may be a Secure Digital (SD) memory card with a series of contacts that act as the interface element **250**. The processing-device interface element **150** may be an expansion slot that receives the contacts of the memory card. The processing device **100** and the portable device **200** may comply with SDIO (Secure Digital Input Output) interface specifications. Other memory card formats having different interface specifications may be employed. However, having an SDIO is advantageous because many processing devices such as PDAs, HPCs and smart cellular phones include an expansion slot that is SDIO compatible.

Additionally or alternatively, the interface elements **150** and **250** also may enable the processing device **100** and the portable device **200** to communicate via a radio-frequency (RF) link (e.g., a short-range RF telemetry), such as Bluetooth® wireless technologies, Zigbee, Z-Sense™ technology, FitSense, BodyLAN™ system, and other RF technologies. RF technologies such as Bluetooth® enable external devices to communicate wirelessly with, for example, laptop personal computers and mobile phones. Other wireless, or non-physical, communication technologies, such as infrared (IR) links, also may be used.

Preferably, the storage service **200** employs an interface element **250** that is compatible with at least one interface technology, or protocol, such as USB, SD, or Bluetooth® technology. If a widely-used interface technology is used, the processing device **100** is more likely to provide native support for the interface with the storage service **200**. In this way, the data-management software **210** on the portable device **200** may be immediately executed on different types of processing devices **100** having varying operating systems and hardware configurations, making the data-management system **10** more portable.

The flowchart of FIG. 2 illustrates how the data-management software **210** on the portable device **200** may be implemented on the processing device **100**. In act **302**, the processing device **100** is initially connected to the portable device **200**. As discussed previously, the processing-device interface element **150** and the portable-device interface element **250** may establish this connection according to an interface technology. For example, the user may insert a USB connector on the portable device **200** into a USB port on the processing device **100**.

As also discussed previously, the processing device **100** may provide native support for the interface technology employed by the portable device **200**. Thus, the processing device **100** can immediately communicate, in act **304**, according to the existing configuration of the portable device **200**. If the portable device **200** employs a USB MSD configuration and the processing device **100** supports this configuration, communication is established automatically between the processing device **100** and the portable device **200**. Due to the wide use of USB interfaces, additional programs, agents, device drivers, or other software components do not generally have to be pre-installed on the processing device **100** to make the processing device **100** compatible with the USB MSD configuration on the portable device **200**.

In act **306**, the processing device **100** detects the portable device **200**. In FIG. 1A, the data-management software **210**

includes the startup program 212. In act 308, the startup program 212 may be launched once the processing device 100 detects the portable device 200. The startup program 212 may be launched automatically or upon input from the user, another person, or another component. Many operating systems provide an auto-launch feature that allows the system to take some action immediately upon the insertion of removable media, such as a CD-ROM, DVD-ROM, or flash media. The processing device 100 may employ a version of the Microsoft® Windows® operating system that provides the AutoRun, or AutoPlay, feature that automatically launches the startup program 212. For some processing devices 100, such as those that employ the Microsoft® Windows® operating system, the portable device 200 may first have to announce to the processing device 100 that it is a non-removable device before the auto-launch feature of the operating system is triggered to run the startup program 212.

In act 310, the startup program 212 reconfigures the portable device 200 from the initial USB MSD configuration to a new configuration specific to the data-management software 210. The new data-management configuration allows the data-management application to be launched and operated in combination with the processing device 100, in act 312. The data-management configuration also supports related functions such as managing updates to the data storage 214.

Reconfiguring the portable device 200 from the more universal USB MSD configuration to the specific data-management configuration can prevent or inhibit other applications on the processing device 100 from accessing the files and data on the portable device 200, thereby making the data-management system 10 more secure. If the processing device 100 employs the Microsoft® Windows® operating system, the Windows® Explorer program, which provides a graphical user interface for accessing the file systems, is unable to access the files on the portable device 200 when the portable device 200 has been reconfigured specifically for the data-management application. This reconfiguration may occur automatically upon connection between the portable device 200 and the processing device 100, thereby preventing non-designated applications on the processing device 100 from accessing any data on the portable device 200.

Due to the plug-n-play aspects of the interface between the processing device 100 and the portable device 200, the processing device 100 and the portable device 200 may be connected or disconnected by the user at any time. As such, the data-management system 10 also ensures that the data or software on the portable device 200 is not corrupted when the portable device 200 is connected or disconnected from the processing device 100. Checksum and/or data commit routines may be employed to ensure that data is successfully transferred and stored, thus promoting the preservation of data integrity. In addition, as discussed previously, when the portable device 200 is disconnected, the data-management software 210 may perform a clean-up or termination procedure to remove any data stored temporarily on the processing device 100, e.g., RAM, and exits gracefully.

Although the portable device 200 and the data-management software 210 stored thereon may be compatible with a variety of processing devices 100 having different operating systems, the data-management system 10 may also employ another processing device 100 that acts as a base-station. The portable device 200 may connect with the base-station processing device using the interface technologies described herein. The base-station processing device may provide a

repository for longer term storage of data downloaded from the portable device 200. In addition, a master version of the data-management application may be launched from the portable device 200 with the base-station processing device. For example, the base-station processing device may be an individual's home PC.

In addition, the portable device 200 may be provided with an expansion port that can receive additional devices, such as an SD memory card. The interface at this expansion port operates similarly to the other interfaces described herein. In particular, the interface may employ an SDIO interface to accept an SD card. The additional memory on the SD card can be used to store a larger database for test results.

In addition to storing data, such as test results from a blood glucose-measurement system and other health data processed by the data-management software 210, the portable device 200 may be employed to incorporate the function of a portable medical records device, due to its portability and compatibility. As such, the portable device 200 may be used to facilitate the sharing of important information with emergency medical technicians (EMT's), doctors, other health care providers, or the like.

In a particular embodiment, the portable device 200 may provide important information during emergency situations. If the user is unconscious or otherwise unable to communicate with a care giver, the care giver may connect the portable device 200 with a processing device 100 via interface element 250 and once the data-management software 210 is launched, important information may appear on a splash screen or initial screen. This type of functionality is possible, because the portable device 200 is highly compatible with a variety of processing devices 100, and the care giver does not have to pre-install software components on the processing device 100 to launch the software 210.

In some cases, the data-management system software 210 may be distributed to the health care community, so that data on the portable device 200 may be accessed, if authorized, with the data-management system software 210 installed on the health care provider's processing device 100, e.g. PC. For security purposes, data may be encrypted so that it may only be read with a decryption key on the health provider processing device. If an instance of the software 210 is already running on the processing device 100, the software 210 on the portable device 200 may be prevented from launching so that two instances of the software 210 are not running. As the portable device 200 and processing device 100 may have different versions of the data-management system software 210, a procedure may be required to reconcile the different versions. Different versions of the software may organize and store data differently and/or collect different types of data. In other words, the structure of the data storage 214 and the types of data stored therein may depend on the version of software 210. For example, if the health care provider's processing device has a newer version of the software 210, the newer version may be developed to be backward compatible with older versions of the software 210 and can operate on the data on the portable device 200. If, however, the health care provider's processing device 100 has an older version of the software 210, the older version 210 may terminate and the newer version on the portable device 200 may be launched on the health care provider's processing device 100. Other techniques for reconciling different versions may be employed. For example, the software 210 may be developed to provide a base set of functions that always operate the same way and to structure certain basic types of data, e.g., fluid analyte measurements,

in the same way, so that at least some aspects of the software **210** are unchanging and thus forward and backward compatible.

In general, the types of data that can be stored and shared with other individuals, such as health care providers, include, but are not limited to: name and address information; data tracked for a disease state (logbook information, daily tracking for chronic illnesses and measurable markers, measurements collected over the last 12 hours, etc.); comorbidity data; last dose of insulin or other medication taken; primary doctor's name and contact information; information on past visits to a doctor; a living will; information on a health care proxy; insurance information; allergy information; and other user-provided information. Alternatively or additionally, information can be provided on a sticker or other label affixed to the portable device **200**.

To preserve the user's privacy, information shared through the portable device **200** is strictly controlled by the user. As a further technique for controlling shared data, the data-management software **210** may provide multiple levels of access so that certain types of data are only accessible to certain individuals/organizations. For example, an EMT may only be able to access information such as doctor's information and data generally available on a medical bracelet. In other words, the software provides very basic functionality, e.g., displaying a single splash screen, to present less sensitive personal information to those without higher authority. Meanwhile, a doctor may be able to access more sensitive health-related information. Furthermore, greater access may be provided to relatives or close care givers, e.g., parents of a child with diabetes.

As described previously, the portable device **200** may include a variety of interfaces **250** to connect and communicate with a variety of devices. In addition to connecting with a processing device **100** to launch data-management software **210** as described previously, the portable device **200** may employ its communication capabilities to connect remotely, e.g., over a network, with external systems to provide the user with a wider range of functionalities and features. In some embodiments, these external systems may provide a host function that manages the communication between the portable device **200** and these external systems. These external systems may execute aspects of the data-management software **210** or other software components stored on the portable device **200** to enable the communication between the portable device **200** and the external systems. Alternatively, these external systems may store the necessary software components locally.

Accordingly, the portable device **200** may connect to an intermediate device, such as a PC with access to the Internet or a mobile communications device with access to a cellular network, to transmit data remotely to other individuals, e.g., health care providers. As such, a user does not have to connect the portable device **200** directly with the other individual's processing device **100** to share data. The health data stored on a portable device **200** is therefore easily shared with other individuals, including health care specialists who may be located in distant or remote locations. This feature may be particularly advantageous for users unable to a health care provider's facilities due to health problems, distance, cost, etc. Moreover, this feature enhances the health care provider's ability to monitor a user's health data with greater frequency and immediacy. The transmission of the data may be managed by the intermediate device, which may include a processor to execute the appropriate software components stored on the intermediate device or on the portable device **200**.

In addition, the portable device **200** may connect to an intermediate device to receive field upgrades to the data and/or software stored on the portable device **200**. For example, the portable device **200** may conveniently receive an updated/patched version, or even a completely new version, of the data-management software **210** by connecting to a remote download server through a networked PC or a mobile communications device. As a further example, the portable device **200** may receive new or updated parameters for the execution of software on the portable device **200**. In some embodiments, new programs or features for the data-management system **10** may be received, e.g., purchased, from a remote download server. Optional features that may customize or personalize the graphical user interface for the data-management application may be available through a system accessible through the Internet. To maintain the integrity of the data and software on the portable device **200**, data or software downloaded via field upgrade may be validated before being employed in the portable device **200**. For example, checksum routines may be employed to confirm that data or software has been successfully downloaded in its entirety. The field upgrade may be managed by the intermediate device, which may include a processor to execute the appropriate software components stored on the intermediate device or on the portable device **200**. Additionally or alternatively, the portable device **200** may include a processor that can locally execute software components to manage aspects of the field upgrade. For example, the processor on portable device **200** may preserve data integrity on the portable device **200** according to a data update file (DUF) or other component that ensures that the software has been successfully downloaded. For additional data security, the DUF be employed with data encryption/decryption.

As discussed previously, embodiments of the portable device **200** may employ a USB interface to connect to a variety of devices. In conventional systems, standard USB is designed to provide connectivity between a processing device and peripheral devices, where the processing device acts as a host and the USB-enabled peripheral devices act as slaves. In general, with standard USB, only the USB host can initiate data transfers to the connected USB peripheral device, and the USB peripheral device can only respond to instructions given by the host. Thus, a USB-enabled peripheral device is not able to connect with other USB-enabled peripheral devices over a peer-to-peer communication channel. In FIG. 1B, where the processing device **100** is a laptop PC, one may consider the laptop PC to be a host and the portable device **200** to be a peripheral device. Once the software **210** is launched on the processing device **100**, the processing device **100**, via the software **210**, may control the execution of program instructions and any data transfer with the portable device **200**.

In other embodiments, however, the portable device **200** may include processing capabilities to act as a host. Therefore, the portable device **200** is not limited to the role of a slave as a peripheral device according to standard USB. In other words, the portable device **200** can communicate with a larger variety of devices via peer-to-peer communication, including devices that are conventionally considered to be peripheral devices.

For example, the portable device **200** may employ the USB 2.0 specification and USB On-The-Go (USB OTG), which is a supplement to the USB 2.0 specification. The USB OTG functionality enables the portable device **200** to communicate with other devices employing USB OTG. When two devices with USB OTG functionality connect with each other directly, a Host Negotiation Protocol (NHP)

enables either one of the two devices to be a host. The NHP also enables the two devices to exchange host/slave roles. When a physical connection between two devices with USB OTG is established, one of the devices assumes the role of the host and powers up the USB V_{BUS} with 8 mA current, so that USB data communication is realized between the two connected devices. A Session Request Protocol (SRP) may be used to prompt the host to turn on the USB V_{BUS} . The communication between the two devices is bi-directional or duplex, so data can be exchanged between the two devices. The communication can provide either low speed transfer (e.g., approximately 1.5 Mbits/sec), full speed transfer (e.g., approximately 12 Mbits/sec), or high speed transfer (e.g., approximately 480 Mbits/sec). Advantageously, USB OTG functionality is configured for use with battery-powered devices and tries to minimize power consumption. In this regard, the USB V_{BUS} can be turned on and off by the host using the SRP.

It is also noted that if the portable device **200** in FIG. 1A includes USB OTG functionality and connects to a processing device **100** (without USB OTG), the processing device **100** and the portable device **200** can communicate via standard USB and the processing device **100** generally operates as the host as described previously. Other portable devices may employ communication protocols that provide advantages similar to those of USB OTG.

In an implementation of USB OTG, the portable device **200** may be connected directly with a USB-enabled printer and the data from the portable device **200** can be automatically printed. The portable device **200** may dynamically create ready-to-print or printable files and may send the files to a printer via the USB connection.

Device drivers and/or other software components may be required for the portable device **200** to interact with another device. For example, a printer driver may be required to print data that is uploaded to a printer. Thus, to print files, the portable device **200** may store and access the printer driver when the portable device **200** connects to the printer to print data. Because it may not be possible to install additional device drivers and/or other software components to the portable device **200** with USB OTG after the portable device **200** is manufactured, the portable device **200** may only be compatible with a preselected set of devices, where drivers for the set of devices were installed onto the portable device **200** during manufacturing. A list of compatible devices may be stored on the portable device **200**, so that the portable device **200** can determine whether it is compatible with a given device.

In another example, a first portable device **200** with USB OTG can communicate directly with a second portable device **200**, where one of the portable devices assumes responsibility as a host. As such, in one application, when a user wants to replace an old portable device with a new portable device, the data and configuration on the old portable device can be transferred easily and directly to the new portable device. In another application, the functionality available with the first portable device **200** may be shared with the second portable device **200**, or vice versa. For example, the second portable device **200** may include interface elements that employ USB as well as an RF wireless protocol not available on the first portable device **200**. However, if the first portable device **200** connects to the second portable device **200** via USB, the first portable device **200** may have access to the RF wireless protocol on the second portable device **200**.

Data, such as test results from a blood glucose-measurement system, may be received by the data-management

system **10** according to a variety of techniques. As the previous discussion of USB OTG indicates, the portable device **200** is not limited to interfacing with processing devices for launching software. Thus, in FIG. 3, the portable device **200** may connect directly with a measurement system **20** to enable data to be directly downloaded from the measurement system **20** onto the portable device **200**.

FIG. 3 illustrates an exemplary measurement system **20** including a meter **500** with a port **502** for receiving and analyzing a fluid sample on a test sensor **400**. The test sensor **400** is configured to receive a fluid sample that is analyzed using the meter **500**. Analytes that may be analyzed include glucose, lipid profiles (e.g., cholesterol, triglycerides, LDL and HDL), microalbumin, hemoglobin A_{1c}, fructose, lactate, or bilirubin. Analyte information may, such as analyte concentrations, may be determined. The analytes may be in a whole blood sample, a blood serum sample, a blood plasma sample, other body fluids like ISF (interstitial fluid) and urine, and non-body fluids.

The test sensor **400** includes a fluid-receiving area (not shown) for receiving a fluid sample. A user may employ a lancet or a lancing device to pierce a finger or other area of the body to produce a fluid sample at the skin surface. The user may then collect this sample (e.g., blood sample) by placing the test sensor **400** into contact with the sample. The fluid-receiving area may contain a reagent that reacts with the sample to indicate the information related to an analyte in the sample, such as analyte concentration.

The test sensor **400** may be an electrochemical test sensor. An electrochemical test sensor typically includes a plurality of electrodes and a fluid-receiving area that contains an enzyme. The fluid-receiving area includes a reagent for converting an analyte of interest (e.g., glucose) in a fluid sample (e.g., blood) into a chemical species that is electrochemically measurable. The reagent typically contains an enzyme, such as glucose oxidase, which reacts with the analyte and with an electron acceptor such as a ferricyanide salt to produce an electrochemically measurable species that can be detected by the electrodes. Other enzymes may be used to react with glucose such as glucose dehydrogenase. In general, the enzyme is selected to react with the desired analyte or analytes to be tested so as to assist in determining an analyte concentration of a fluid sample. If the concentration of another analyte is to be determined, an appropriate enzyme is selected to react with the analyte.

Alternatively, the test sensor **400** may be an optical test sensor. Optical test sensor systems may use techniques such as transmission spectroscopy, absorption spectroscopy, diffuse reflectance, fluorescence spectroscopy, fluorescence resonance energy transfer, combinations thereof, and others for measuring the analyte concentration. An indicator reagent system and an analyte in a sample of body fluid react to alter light that is directed to the sensor **400**. The degree of light alteration is indicative of the analyte concentration in the body fluid.

Some commercially available test sensors that may be used include those that are available commercially from Bayer HealthCare LLC (Tarrytown, N.Y.). These test sensors include, but are not limited to, those used in the Ascensia® CONTOUR® blood glucose monitoring system, the Ascensia® BREEZE® and BREEZE®2 blood glucose monitoring system, and the Ascensia® Elite® and Elite® XL blood glucose monitoring system. Other test sensors, in addition to the ones listed above, may be incorporated into the methods and systems of the present invention.

In FIG. 3, the meter **500** receives and engages the test sensor **400**. The meter **500** measures the concentration of

analyte for the sample collected by the test sensor 400. The meter 500 may include contacts for the electrodes to detect the electrochemical reaction of an electrochemical test sensor. Alternatively, the meter 500 may include an optical detector to detect the degree of light alteration for an optical test sensor. To calculate the actual concentration of analyte from the electrochemical or optical reaction measured by the meter 500 and to generally control the procedure for testing the sample, the meter 500 employs at least one processor 510, which may execute programmed instructions according to a measurement algorithm. Data processed by the processor 510 may be stored in memory 520. Furthermore, the meter may have a user interface 570 which includes a display (e.g., a liquid-crystal display or the like). Pushbuttons, a scroll wheel, touch screens, or a combination thereof, may also be provided as a part of the user interface 570 to allow a user to interact with the meter 500. The display typically shows information regarding the test results, the testing procedure and/or information in response to signals input by the user.

Although the meter 500 can store test results and provide a user interface 570 to display test results, the data-management software 210 on the portable device 200 provides more advanced functionality for managing, processing, and displaying test results and related information. Therefore, the test-related data collected by the meter 500 may be downloaded to the portable device 200 for use with the data-management software 210. In FIG. 3, the meter 500 includes an interface element 550 that enables the meter 500 to connect with the portable device 200 via the portable-device interface element 250.

The meter-interface element 550 and the portable-device interface element 250 may employ the interface technologies described previously. A USB interface may connect the portable device 200 with the meter 500. The transfer of data between the meter 500 and the portable device 200 may require a host function, such as the USB host function, to be employed on the portable device or meter 500, which includes a processor 510. As such, the download of data is managed by the portable device 200 or the meter 500 to execute appropriate software components stored on the meter 500 or the portable device 200. Data transferred, e.g., a series of blood-glucose readings, can be organized with timestamps or sequence numbers to ensure appropriate data storage and analysis by the portable device 200.

In addition to the interfaces described previously, other communication protocols for data transfer via interface elements 250 and 550 may be employed. For example, radio frequency identification (RFID) technology can provide an interface for data transfer to the portable device 200 from the meter 500. In particular, interface element 250 on the portable device 200 may include an RFID antenna and RFID circuitry. Meanwhile, the interface element 550 on the meter 500 may include the corresponding RFID circuitry, so that the meter 500 can be swiped past or scanned by the portable device 200 to transfer data, such as blood-glucose readings, to the portable device 200. Less power is required for the transmitter, e.g., the meter 500, and more power is required for the receiver, e.g., the portable device 200, to employ this RFID interface. In some embodiments, data in the range of about 56K to about 256K, which may correspond for example to about 100 blood-glucose readings, can be transferred at one time.

The RFID technique for transferring data may be employed between the portable device 200 and any other device, such as a processing device 100. As described previously, the processing device 100 may be a base-station

processing device or a health care provider's processing device. Because these processing devices may already include the data-management software 210, the software 210 does not have to be launched from the portable device 200 and only stored data, such as data associated with blood-glucose readings, needs to be transferred to the processing device 100. In this embodiment, the interface element 150 on the processing device 100 includes the RFID antenna, as the processing device 100 acts as the receiver while the portable device 200 acts as the transmitter. Advantageously, less power is required for the portable device 200 in this embodiment.

The portable device 200 may have a power source such as a rechargeable battery 260, which may be recharged via the connection with the processing device 100 or another external device with a power supply. For example, power may be transferred via a USB connection between the processing device 100 and the portable device 200. When the portable device 200 and the meter 500 are connected, the battery 260 can be used to recharge the rechargeable battery 560 which powers the meter 500, or vice versa.

As described previously, the portable device 200 may connect to an intermediate device to receive field upgrades to the data and/or software stored on the portable device 200. The portable device 200 may also be used to update or add software to the meter 500. In an exemplary embodiment, a new or updated version of software for the meter 500 may be downloaded to the portable device 200. This may be accomplished after the portable device 200 connects to a remote download server through a networked PC or a mobile communications device. The new or updated version of software may then be downloaded to the meter 500 after the meter 500 is connected to the portable device 100. This download process may be managed by the portable device 200 or the meter 500.

In FIG. 4, data collected by the measurement system 20 of FIG. 3 may be downloaded by connecting the measurement system 20 to the processing device 100 through processing-device interface element 155, while the portable device 200 is also connected to the processing device 100. The data can then be loaded onto the portable device 200 via the processing device 100. The connection between the measurement system 20 and the processing device 100 may employ the communication interface technologies described previously. For example, the measurement system 20 may be received into a second USB port on the processing device 100. In addition, the data-management software 210 running on the processing device 100 may be used to enable or facilitate the transfer of data from the measurement system 20.

FIG. 5 illustrates another portable device 1100 that incorporates the components and functions of the portable device 200 with the components and functions of the meter 500. In particular, the portable device 1100 includes a memory 220 storing a software 1110 that may be launched on the processing device 100 without requiring the pre-installation of software components on the processing device 100. The software 1110 includes a startup program 1111 that launches the software 1110 on the processing device 100 in the manner described previously. In addition, the memory 220 may include data storage 1112, such as a database, that stores data collected or processed with the software 1110. The memory 220 may include a universal serial bus (USB) flash drive, a memory card, or the like. The portable device 1100 also has an interface element 250 that may connect to the interface element 150 of the processing device 100 via USB technology, RF technology, or the like.

In addition, the portable device **1100** may include a port **502** to receive an analyte-test sensor **400**. A sample, such as a blood sample, may be collected by the test sensor **400** and may be analyzed as described previously to determine an analyte concentration, such as a blood glucose concentration. The software **1110** includes programmed instructions for analyzing the sample received with the analyte-test sensor **400**. As such, when the software **1110** is launched on the processing device **100**, the processor **110** on the processing device **100** executes the software **1110** to collect and analyze information from the detection of an electrochemical or optical reaction when the sample reacts with a reagent on the test sensor **400**. Once the processor **110** determines test results from analyzing the sample on the test sensor **400**, the processing device **100** may display the test results on the display **120** associated with the processing device **100**. Accordingly, the portable device **1100** and the processing device **100** combine to provide a measurement system, such as a blood glucose meter, where the portable device **1100** provides the port **502** for detecting a reaction on the test sensor **400** and the processing device **100** analyzes the reaction with the software **1110** from the portable device **1100** and displays the test results. Additionally, the software **1110** may include features of the data-management software **210** described previously to provide enhanced data processing and display features on the processing device **100**.

The memory **220** of portable device **1100** may include a Secure Digital (SD) card and the portable device **1100** may connect with a processing device **100**, such as a PALM® handheld or Blackberry® device, via SDIO (Secure Digital Input Output) interface specifications. The portable device **1100** may therefore have the form of a SD card with the port **502** for receiving a test sensor **400**, and the SD card can be plugged into a processing device **100** to provide a measurement system. Alternatively, the portable device **1100** may include other types of memory and may connect to the processing device via other technologies, such as Bluetooth® wireless technologies.

Additionally, the software **1110** may be Java based so that the portable device **1100** can use a web browser as commonly available on most operating systems to render, via HTML, a front-end user interface for the software **1110**. Advantageously, the Java based software **1100** is generally not dependent on the operating system type, and many devices, such as a PALM® handheld or Blackberry® device, employ web browsers. Thus, the portable device **1100** provides a highly compatible and portable approach for converting many devices into a measurement system, such as a blood glucose meter. In general, the software launched by the portable devices described herein may also be Java based programs that are executable on web browsers and similar rendering applications.

Like the portable device **1100** of FIG. 5, an integrated device **600** in FIGS. 6A-6D incorporates the components and functions of the portable device **200** with the components and functions of the meter **500**. Accordingly, the integrated device **600** may receive an analyte-test sensor **400** via the port **502**. However, the integrated device **600** also includes a processor **610** that may calculate the concentration of analyte in the sample collected by the test sensor **400**. Unlike the portable device **1100**, the integrated device **600** does not require the calculation of analyte to be handled by a processor **110** of a separate processing device **100**. Rather, the processor **610** in the integrated device **600** processes information from the detection of a reaction between the sample and a reagent on the test sensor **400**. The test results are stored in the memory **220** of the integrated device **600**.

As such, the memory **220** may have a capacity in the range of about 500 MB to about 2 GB.

In addition, the integrated device **600** includes a user interface **670** that may be used to display the test results and to enter input for various display options. In particular, the user interface **670** may provide further convenience and portability for a data-management system **10** by integrating the functionality of the portable device **200** with advanced data processing and display features. In sum, the integrated device **600** integrates the portable device **200** with a user interface **670** as well as the components and functions of the meter **500**.

Thus, as shown in FIGS. 6B and 6C, an integrated device **600** may be a portable blood glucose meter that provides data processing and display features. Users may employ the integrated device **600** to provide a blood sample via test sensor **400** and may access more sophisticated presentations of blood glucose test data from the integrated device **600** without launching the data-management application on a separate processing device **100**.

However, as hardware limitations may still prevent all desired functionality to be incorporated into the integrated device **600**, the integrated device **600** retains the ability to launch the data-management application on a larger processing device **100** and to provide the user with functionality not available on the integrated device. FIG. 6D illustrates the integrated device **600** connected wirelessly to more than one processing device **100**, including a laptop PC and mobile communication devices.

As described above, the integrated device **600** may communicate with, and transfer data to, a processing device **100** without necessarily launching the software **210**. Indeed, the processing device **100** may already include the data-management software **210**. In particular, the RFID technique for transferring data can be employed between the integrated device **600** and the processing device **100**. The interface element **150** of the processing device **100** includes the RFID antenna, as the processing device **100** acts as the receiver while the integrated device **600** acts as the transmitter. The integrated device **600** may be swiped past or scanned by the processing device **100** to transfer data, such as blood-glucose readings, to the processing device **100**. Less power is required for the integrated device **600**, and more power is required for the processing device **100**. Data transferred, e.g., a series of blood-glucose readings, can be organized with timestamps or sequence numbers to ensure appropriate data storage and analysis by the processing device **100**.

In further applications, the integrated device **600** may transmit data to a processing device **100** that resides remotely on a network. As described previously, various approaches can be implemented to provide networked communications. For example, the integrated device **600** may connect to an intermediate device, such as a PC with access to the Internet or a mobile communications device with access to a cellular network, to transmit data remotely to other systems or devices. In other embodiments, the integrated device **600** may communicate more directly with a remote system or device. For example, a remote processing device **100** may be a server in a centralized health care system that provides further processing or storage of data collected by the integrated device **600**. The centralized health care system may provide a web-based or a client-server based front end to data-management software **210** running on the remote processing device **200**. Additionally or alternatively, the data may be shared with health care professionals. Accordingly, to transfer data from the integrated device **600** to the remote processing device **100**, the

integrated device **600** may connect directly via the interface element **250**, for example, to a wireless network or a Wi-Fi hotspot. Data encryption and authentication procedures may be employed to ensure data security. In one embodiment, the integrated device **600** detects the presence of a wireless network or a Wi-Fi hotspot and automatically transfers data to the remote processing device **100** through a background process. Alternatively, the integrated device **600** may alert the user via the user interface **670** that access to the remote processing device **100** is available, and the user can initiate data transfer if desired.

The integrated device **600** may store a display state for the user interface **670**. For example, functionality may be available on the integrated device **600** to log testing information and a log book may be displayed on the display of user interface **670**. The log book function may be accessed by selecting a shortcut icon on the screen or selecting the function through a menu. However, for convenience, when the user displays the logbook, the integrated device **600** tracks the state of the display, so that if the device **600** is powered off, enters a standby mode, or is otherwise deactivated during the logbook function, the logbook function and display can be started automatically when the device **600** is activated again. Of course, the display state may also be used for any other function that appears on the display.

Moreover, the display state stored by the integrated device **600** may be used with data-management software **210** that runs on the processing device **100**. In particular, the user may display some information, such as a summary of test results, through the user interface **270** of the integrated device **600**. If this particular display remains in the display state, the display state may be communicated to the data-management software **210** on the processing device **100** when it is connected to the integrated device **600**, so that functionality in the data-management software **210** that corresponds to the display last shown on the device **600** may be automatically started. The data-management software **210** may automatically start a screen that provides detailed data regarding a summary of test results displayed on the integrated device **600**.

In general, the portable device **200** may be integrated with varying levels of functionalities, such as user interface features and measurement system capabilities. However, any device employing components and functions of the portable device **200** may include a user interface, even if it does not incorporate components and functions of the meter **500**.

FIGS. 7A-10B illustrate additional features that may be employed with the exemplary embodiments described previously. Although these features are described with respect to embodiments with a USB interface element **250**, the features may be applied to embodiments employing other communication protocols for interface element **250**, as discussed previously.

FIGS. 7A and 7B illustrate a portable device **700** which may be similar in many respects to the portable device **200** described previously. The portable device **700** includes a USB interface element **250A** that may extend from the body, or a housing portion, of the portable device **700** to keep the body from physically interfering with the insertion of the interface element **250A** into a USB port of a processing device **100**. In particular, a conducting cable **252** of convenient length extends between the interface element **250A** and the body **201** of the portable device **700**. The conducting cable **252** enables the interface element **250A** to communicate electrical signals to other components of the portable device **700**, while the interface element **250A** is spaced away

from the body **201** of the portable device **700**. To provide convenient storage of an unnecessary length of the conducting cable **252**, a portion of the interface element **250A** includes a storage chamber **251**. The storage chamber **251** of FIG. 7A includes a spring-loaded cable recoil with a clutch, which draws any slack in the conducting cable **252** into the storage chamber **251**. The conducting cable **252** maintains an appropriate amount of tension, and an additional length of the conducting cable **252** can be easily drawn from the storage chamber **251** when extra length is required. When the interface element **250A** is not in use, it can be conveniently stored in the storage cavity **253** in the body **201** of the portable device **700**. FIG. 7B illustrates the portable device **700** connected via conducting cable **252** to a processing device **100B**, which is a laptop PC.

FIGS. 8A and 8B illustrate an integrated device **800**, which may be similar in many respects to the integrated device **600**. The integrated device **800** has a USB interface element **250**. The integrated device **800** may be powered by a connection via the USB interface element **250** to either a processing device **100**, such as a PC, or to a battery pack **260**. In FIGS. 8A and 8B, the battery pack **260** is disposed in a cap **202** which fits over the USB interface element **250**. Thus, aesthetically, the battery pack **260** looks like a cap for the USB interface element **250**. The battery pack **260** may be positioned within the cap **202** according to a first orientation, so that when the cap **202** is placed over the USB interface element **250**, the battery pack **260** connects with the USB interface element **250** and provides power to the integrated device **800**. FIG. 8B illustrates the cap **202** in a second orientation where the battery pack **260** is disposed in an offset position so that the battery pack **260** and the USB interface element **250** are not aligned. Thus, when in the second orientation, the battery pack **260** does not connect to the USB interface element **250**, enabling the battery power to be saved and the battery life to be extended. The cap **202** may be transitioned between the first orientation and the second orientation by removing the cap **202**, turning the cap **202** 180-degrees, and placing the cap **202** back over the interface element **250**. The battery pack **260** may include one or more replaceable batteries. Alternatively, the batteries are not replaceable and are fixed to the cap **202**, and thus, the entire cap **202** must be replaced to employ new batteries.

FIGS. 9A and 9B illustrate another integrated device **900**, which may be similar in many respects to the integrated device **800** described previously. One end of the integrated device **900** includes an USB interface element **250** with a cap **202**. Meanwhile, the other end of the integrated device **900** includes another cap **203** that stores test sensors **400**. The caps **202** and **203** are interchangeable. Thus, during operation, the cap **202** is placed over the USB interface element **250** to connect the battery pack **260** to deliver power, and the cap **203** is removed to provide access to the sensor strips **400** for collecting samples. For example, the cap **203** may hold multiple test sensors **400** that may be used to collect samples, and the test sensors **400** may then interface with the integrated device **800** to capture the sample data. However, when the integrated device **800** is not in use, the cap **203** may be placed over the USB interface element **250**, and the cap **202** may be placed over the other end of the integrated device **800**. The cap **203** may provide a sealing fit over the ends of the integrated device **800** to promote proper storage of the test sensors **400**.

FIG. 10A illustrates yet another integrated device **1000**, which may be similar in many respects to the integrated device **600**. The integrated device **1000** includes a USB interface element **250** in a main body **201**. A cap **209** may

be removably coupled to the main body **201** and placed over the USB interface element **250**. The cap **209** includes a temperature sensor **280** and corresponding circuitry **281**. The temperature sensor **280** may include a thermocouple, thermistor, thermochromatic sensor, or the like. The temperature sensor **280** measures the temperature at, or near, an outer surface **204** of the cap **209**. When the cap **209** is placed over the USB interface element **250**, the temperature sensor **280** is connected to the interface element **250** and corresponding temperature data is transferred to the processor of the integrated device **1000**. In general, the temperature of the main body **201** may not reflect the ambient temperature, because the main body **201** may retain heat generated by the operation of the integrated device **1000**. The temperature of the main body **201** may also be affected by its proximity to other warm or cold bodies. For example, body heat may be transferred to the main body **201** when the integrated device **1000** is held in a user's hands or is otherwise carried in proximity to the user's body. Due to the thermal mass of the main body **201**, the main body **201** may reach equilibrium with the ambient very slowly. Because the outer surface **204** of the cap **209** has a weak thermal coupling with the main body **201**, however, the temperature measured at, or near, the outer surface **204** is not substantially affected by the main body **201**. Moreover, the temperature of the temperature sensor **280** reaches equilibrium with the ambient more quickly than the main body **201**. A heat sink may be employed to speed up the transition to ambient temperature for the outer surface **204**. As a result, the temperature sensor **280** reflects the ambient temperature more accurately. The temperature data from the temperature sensor may be employed to determine the concentration of an analyte in a fluid sample (e.g., blood glucose concentration) according to a reaction with the reagent on the test sensor **400**. Because the level of reaction may be affected by changes in temperature of the reagent, the ambient temperature can be measured to estimate the temperature of the reagent. As such, the integrated device **1000** may account for the reagent's sensitivity to temperature and, thus, obtain a more accurate calculation of the concentration of analyte in the sample.

FIG. 10B illustrates a cross-section of a cap **209** with a temperature sensor **280** that may be employed with the integrated device **1000** of FIG. 10A. In particular, the temperature sensor **280** includes a thin membrane **205** in a part of an outer wall portion **206** of the cap **209**. The thin membrane **205** has a low thermal mass and a large area-to-thickness ratio that helps the thin membrane to reach equilibrium with the ambient more quickly. As such, the temperature sensor **280** measures the temperature of the thin membrane **205** to achieve a more accurate determination of the ambient temperature. To minimize heat conduction to the thin membrane **205**, the thin membrane **205** may be formed of plastic or the like, and the outer wall portion **206** may be coupled to the rest of the cap **209**, so that there is at least one gap **207** between the outer wall portion **206** and the rest of the cap **209**. The gap **207** allows ambient air flow around the thin membrane **205** to promote transition by the thin membrane to the ambient temperature. Alternatively, the outer wall portion **206** may provide a very loose interlocking connection that includes gaps **207** and allows ambient airflow around the thin membrane **205**. The thin membrane **205** or the outer wall portion **206** may be replaced if either experiences any damage. The temperature sensor circuitry **281** may include an infrared (IR) sensor to measure the temperature of the thin membrane **205**. Alternatively, the thin membrane **205** may include a thermochromic material,

which changes color with temperature. The temperature sensor **280** in this case may include a light source, such as one or more laser LED's, and a detector, such as one or more photodiodes. The light source transmits photons to the thermochromic material, and the detector receives the photons that are reflected from the thermochromic material and that indicate the color of the thermochromic material. In some embodiments, the circuitry **281** may be housed in the main body **281** rather than the cap **209**, while the thin membrane **205** or other temperature sensor structure remains in the cap **209**.

While the invention is susceptible to various modifications and alternative forms, specific embodiments and methods thereof have been shown by way of example in the drawings and are described in detail herein. It should be understood, however, that it is not intended to limit the invention to the particular forms or methods disclosed, but, to the contrary, the intention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the invention.

What we claim is:

1. A system for securing health data, comprising:

a blood glucose meter including:

a housing having a port configured to receive a test sensor therein;

a measurement system disposed within the housing, the measurement system coupled with the test sensor when the test sensor is received in the port of the housing, the measurement system including at least one processor that executes program instructions to determine a glucose concentration measurement of a blood sample received by the test sensor; and

a data storage system disposed within the housing, the data storage system including a first memory device storing a data-management application and a second memory device storing health data, the health data including glucose concentration measurements determined by the at least one processor of the measurement system from the blood sample received by the test sensor; and

a processing device configured to (i) establish data communications with the blood glucose meter via a data communications interface, (ii) read the data-management application from the first memory device, (iii) read the health data from the second memory device, and (iv) execute the data-management application to process the health data, wherein all other applications executing on the processing device are prevented from accessing the health data stored in the second memory device of the data storage system by the blood glucose meter and the read health data.

2. The system of claim 1, wherein the processing device does not store any component of the data management application before data communications are established between the blood glucose meter and the processing device.

3. The system of claim 1, wherein the processing device processes the health data from the second memory without permanently storing the health data on the processing device.

4. The system of claim 1, wherein the data-management application includes a termination component configured to delete any of the health data transferred to the processing device.

5. The system of claim 1, wherein the data-management software includes a termination component configured to delete any of the health data read by the processing device.

6. The system of claim 1, wherein the second memory device is separate from the first memory device, and wherein second memory device stores health data in an encrypted fashion such that the data-management application is required to decrypt the stored health data.

7. The system of claim 1, further comprising a user interface operable to display at least a portion of the stored glucose concentration measurements, and wherein the processing device displays the processed health data on a display of the processing device, the displayed processed health data being different than the glucose concentration measurements displayed on the user interface.

8. The system of claim 7, wherein the displayed processed health data includes: (i) customizable averages based on the health data; (ii) health data in relation to a user-specified target range; (iii) feedback and predictive analysis related to the health data; or (iv) any combination of (i), (ii), and (iii).

9. The system of claim 1, wherein the processing device is compatible with an interface protocol configuration of the blood glucose meter, the interface protocol configuration allowing data communication to be established between the blood glucose meter and the processing device, and in response to establishment of the data communications between the blood glucose meter and the processing device, the blood glucose meter is reconfigured from the interface protocol configuration to a software configuration allowing the processing device to read the data-management application and the health data from the data storage system, the software configuration being different from the interface protocol configuration, the software configuration including a security component that controls access by the processing device to the health data in the data storage system such that the security component only permits the data-management application access to the health data.

10. A method for securing health data, comprising:
 receiving a test sensor in a port of a housing of a blood glucose meter such that the test sensor is coupled with a measurement system of the blood glucose meter;
 receiving a blood sample via the test sensor;
 in response to the receiving the blood sample, executing program instructions, via at least one processor of the blood glucose meter, to determine a first glucose concentration measurement of the received blood sample;
 storing the determined first glucose concentration measurement in a data storage system of the blood glucose meter, the data storage system including a first memory device storing a data-management application and a second memory device storing glucose concentration measurements including the determined first glucose concentration measurement of the received blood sample via the test sensor;
 establishing by a processing device, for a first time, data communications with the blood glucose meter via a data communications interface; and
 in response to the establishing of the data communications with the blood glucose meter for the first time, (i) reading, with the processing device, the data-management application from the first memory device; (ii) reading with the processing device, the glucose concentration measurements from the second memory device; and (iii) executing, by the processing device,

the data-management application to process the glucose concentration measurements, wherein the blood glucose meter is configured to prevent all other applications executing on the processing device from accessing the stored glucose concentration measurements.

11. The method of claim 10, wherein the processing device does not store any component of the data-management application before data communications are established between the blood glucose meter and the processing device for the first time.

12. The method of claim 10, wherein the processing device processes the glucose concentration measurements without permanently storing the glucose concentration measurements on the processing device.

13. The method of claim 10, further comprising deleting from a memory of the processing device, using a termination component of the data-management application, the glucose concentration measurements read by the processing device.

14. The method of claim 10, wherein the processing device is compatible with an interface protocol configuration of the blood glucose meter, the interface protocol configuration allowing data communication to be established between the blood glucose meter and the processing device, and in response to the establishing of the data communications between the blood glucose meter and the processing device, the method further comprising reconfiguring the blood glucose meter from the interface protocol configuration to a software configuration specific to the data-management application, the software configuration being different from the interface protocol configuration, the software configuration including a security component that controls access by the processing device to the glucose concentration measurements in the data storage system such that the security component only permits the data-management application access to the glucose concentration measurements.

15. The method of claim 10, wherein the second memory device is separate from the first memory device, and wherein the determined first glucose concentration measurement is stored in the second memory device in an encrypted fashion such that the data-management application is required to decrypt the stored first glucose concentration measurement.

16. The method of claim 10, further comprising:
 displaying, on a user interface of the blood glucose meter, the stored first glucose concentration measurement; and
 displaying, with the processing device, the processed glucose concentration measurements on a display coupled to the processing device, the displayed processed glucose concentration measurements being different than the first glucose concentration measurement displayed on the user interface of the blood glucose meter.

17. The method of claim 16, wherein the displayed processed glucose concentration measurements includes: (i) customizable averages based on the glucose concentration measurements; (ii) health data in relation to a user-specified target range; (iii) feedback and predictive analysis related to the glucose concentration measurements; or (iv) any combination of (i), (ii), and (iii).